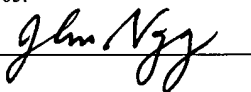


CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on November 17, 2005.

John S. Nagy, Reg. No. 30,664



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/693,577  
Applicant : Lilip Lau, Bill Hartigan  
Filed : October 23, 2003  
Art Unit : 3736  
Examiner : Samuel G. Gilbert  
Title : SELF-SIZING CARDIAC HARNESS FOR TREATING  
CONGESTIVE HEART FAILURE

Docket No.: : PARCR 65971  
Customer No. : 24201

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Dear Sir:

I, BILL HARTIGAN, DECLARE AS FOLLOWS:

1. I am one of the named inventors of the above-captioned patent application and I am an employee of Paracor Medical, Inc., the Assignee of the present application. I am a co-founder of Paracor Surgical, Inc., the predecessor of Paracor Medical, Inc., and I am the Operations Manager.

BEST AVAILABLE COPY



2. I have first-hand knowledge of the facts set forth herein. I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

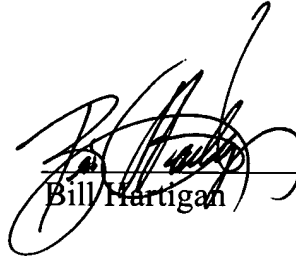
3. I began working on the development of an endocardial harness at a time just before October 8, 1999. All of the development work that I did was conducted in the United States at Palo Alto, California. Prior to October 8, 1999, I and my co-inventor, Lilip Lau, conceived of the subject matter set forth in the claims of the present application.

4. Attached hereto as Exhibit A is a laboratory notebook page, in my handwriting, as evidence of the development work that I did prior to October 8, 1999. The dates have been redacted, however, my signature and the signature of a witness appear on the notebook page. In Exhibit A, I show a photo etched anchor concept in which barbs can extend outwardly from the anchor in order to draw a portion of the myocardium closer together in order to relieve wall stress.

4. Attached hereto as Exhibit B are pages from my laboratory notebook evidencing diligence after October 8, 1999 up to actual reduction to practice, and up to the filing of provisional application Serial No. 60/188,282, filed March 10, 2000. Upon information and belief, I and/or my co-inventor Lilip Lau worked on a daily basis toward an actual reduction to practice and constructive reduction to practice on a cardiac harness. Referring to Exhibit B, we would work in the laboratory developing the cardiac harness and then periodically make entries in my laboratory notebook, which I made on at least the following dates: October 13, 1999; October 28, 1999; November 1, 1999; November 2, 1999; November 3, 1999; November 4, 1999; November 12, 1999; November 15, 1999; November 16, 1999; November 17, 1999; November 19, 1999; November 24, 1999; December 2, 1999; December 9, 1999; December 15, 1999; December 17, 1999; January 31, 2000; February 14, 2000; March 2, 2000; March 13, 2000; and March 16, 2000.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and I acknowledge that any willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and may jeopardize the validity of the application or patent issuing thereon.

Date: 11-15-05

  
Bill Hartigan

106318.1

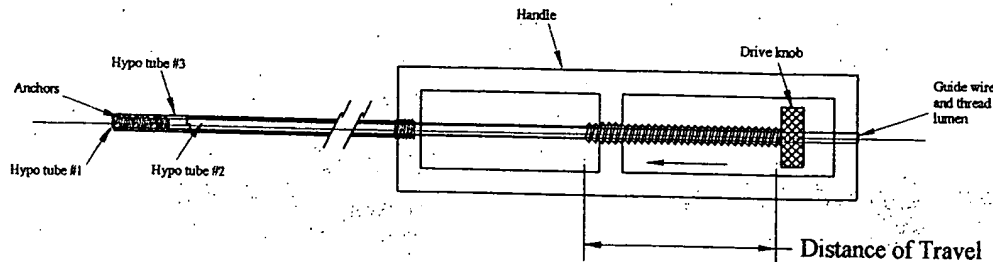


# Concept for Delivery of Wire Anchors

10/13/99

10/12

## Concept for Delivery of Wire Anchors



### 1. Description

- Hypo tube # 1 contains both suture line and guide wire and is fixed to the handle portion. Suture and wire would pass through the entire lumen. The outer diameter would support the coil anchors. Coils for testing are .107 Id x .156" od
- Hypo tube #2 drives the wire anchors by means of a connected lead screw and knob. The distance of travel would be related to the number of anchors on the first hypo tube. The end of the tube closest to the anchors could be notched in order to grasp the end of the coil. As the drive knob is turned, the motion would translate to the first anchor and in turn drive the others. The screw mechanism could be ratcheted in order to drive a single anchor.
- Hypo tube #3 serves as a protective sleeve and prevents the anchors from coming out of plane and binding on each other. The tube is fixed to the handle.

### 2. Materials

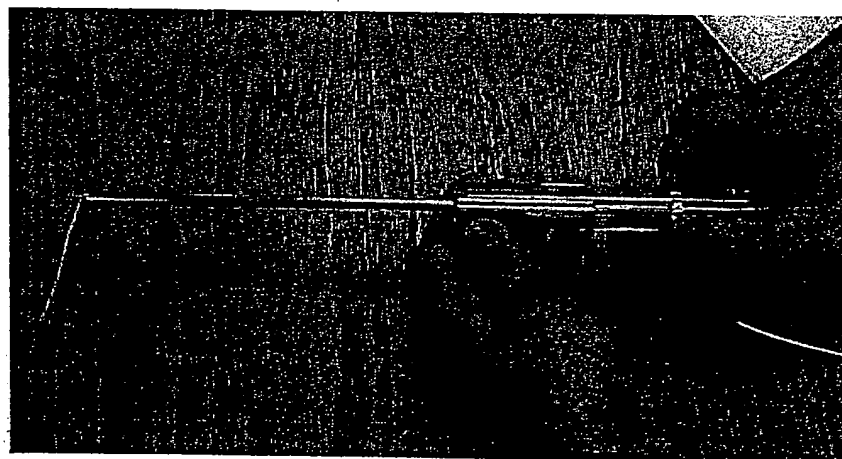
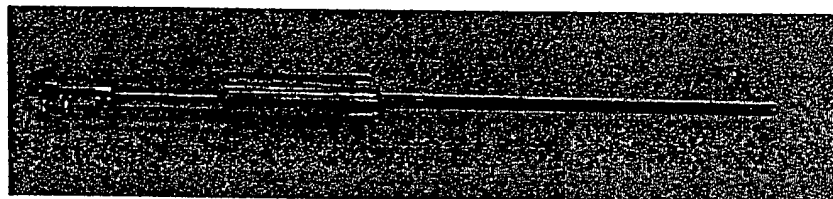
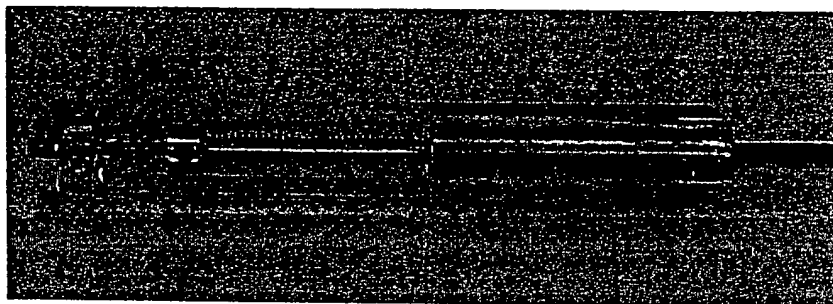
- For prototypes, all hypo tubes will be made from Stainless steel tubing. After proof of concept, shafts will be made of flexible catheter tubing in order to deliver devices percutaneously. Handle portion could be rectangular and machined from plastic or it could be molded to form a handle and trigger.
- Dimensions for tubing :
  1. 8RW .165" x .135" od -id (hypo tube #2)
  2. 10RW .134" x .106" (Hypo tube # 2)
  3. .188 x .156" (hypo tube #3)
  4. 12H .109" x .077" (hypo tube #1)
  5. Tubing lengths : approx. 6"
  6. Handle length: approx. 5-6"

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Prototype Delinsky Device for WICK Anchors

10/18/99



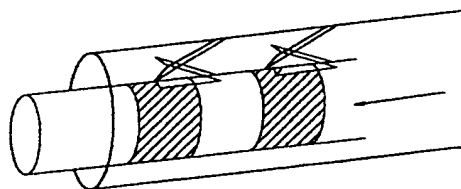
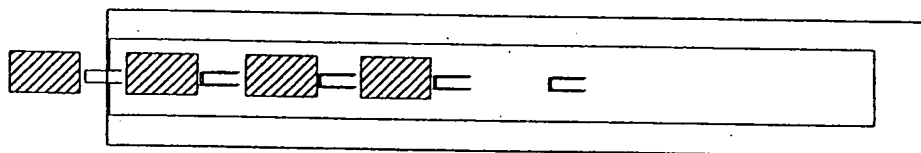
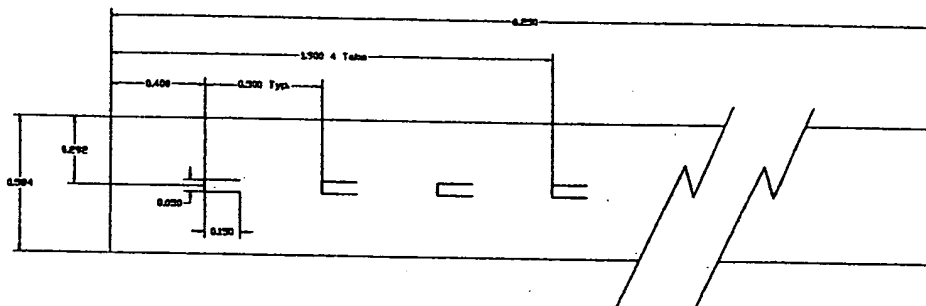
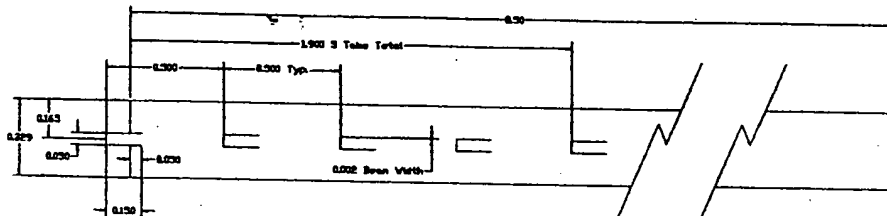
Bill Delinsky  
10/18/99

Wick  
10/28/99

## method for deploying ANCHORS.

10/28/99

Part # 1911



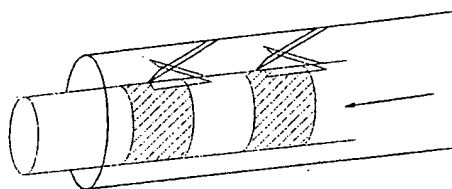
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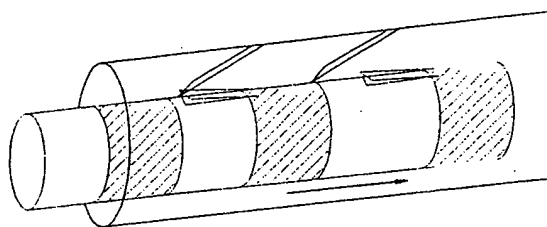
10/28/99

**Method for deploying Anchors**Description:

Deployment would consist of two hypo-tubes; an outer tube with tabs facing inward and able to engage the coil spring anchor and an inner tube with tabs facing outward. As the inner tube is advanced the anchors are engaged in the slots. (Step 1) The outer tube slots slide over the anchors and do not engage the anchor.

**Step 1****Step 2**

As the inner tube is pulled back, the outer tube slots engage the anchor; the inner tube slots are pushed down. As the tabs clear the next anchor, they spring up and allow the next anchor to engage.

**Materials:**

For initial prototypes parts will be made from lasered 316S/S hypo-tubing.

Dimensions: Inner tube - .106"od x .77 id

Outer tube - .188"od x .156" id.

Parts will be cut to dimensions show on opposite page.

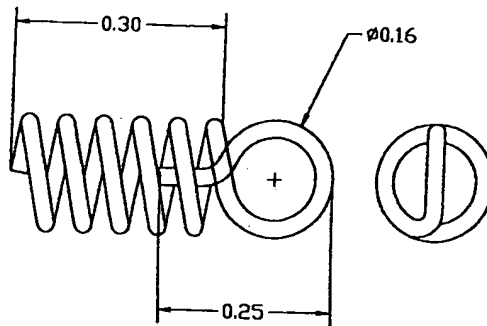
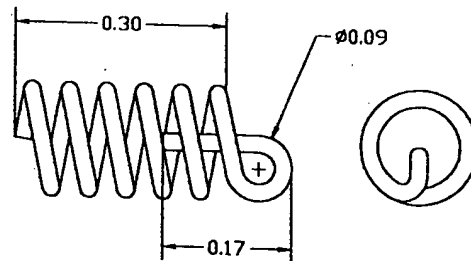
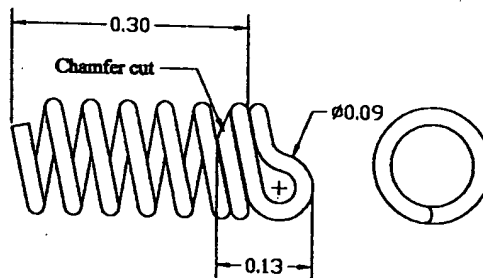
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10/28/99

## Spring Anchor Design Ideas

Part #  
CS-1Part #  
CS-2Part #  
CS-3Confidential

Part Numbers: CS-1, CS-2, CS-3

10/28/99

Paradigm Surgical

D. Ogi (408) 396-8835

Notes:

Material: 316 SS

Wire diameter: 0.023"

Pitch: 20 threads per inch

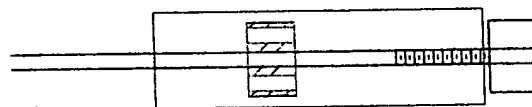
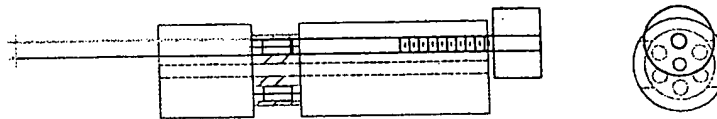
Thread Direction: Right hand thread

Tolerances: +/- .001 ID and OD dimensions

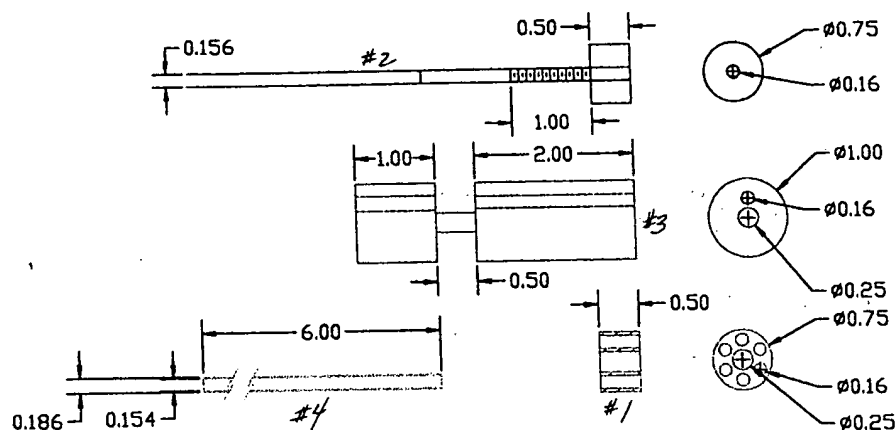
*[Handwritten signatures and initials]*

# Concept for Anchor Delivery.

11-1-89



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## Description:

Method allows one anchor to be deployed at a time by rotating preloaded anchor cartridge (#1). Drive tube (#2) is pulled back allowing anchor to be advanced into housing chamber (#3). Drive tube (#2) is advance to insert thread allowing anchor to be threaded into fissure. Drive thread would be same pitch as anchor. Process is repeated until anchors are deployed.

Notes: Anchors could vary in size and configuration for start & end points, main field anchors or mechanical properties.

(Cont.)

## CONCEPT for WIRE anchor DELIVERY (cont.)

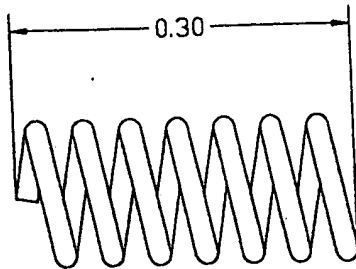
Current anchor deployment uses a Thread linking all deployed anchors together. With this deployment method Thread is not able to be placed in the drive tube because: 1. anchors may be similar to those shown on page 6, threads could become entangled in loops. 2. since anchors are deployed in independent tubes, thread would have to be placed in the center of each spine prior to deployment.

For this deployment method a future lumen will be run along the side of the deployment tube (#4). The tube will be placed at the end where the anchor exits and <sup>will</sup> be placed toward the center of the deployment tube so thread is readily picked up by each advancing anchor.

MATERIALS: for initial prototype parts. housing will be made of acrylic, drive tube from 5/8 soft deployment tube will be 3/8 5/8 hypo tube  
- 188" x .156" ID.

Thread lumen will be attached using heat shrink tubing or 5/8 hypo tube will be spot welded.

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11/1/99  
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11/6/99

*Coil Spring Anchor*

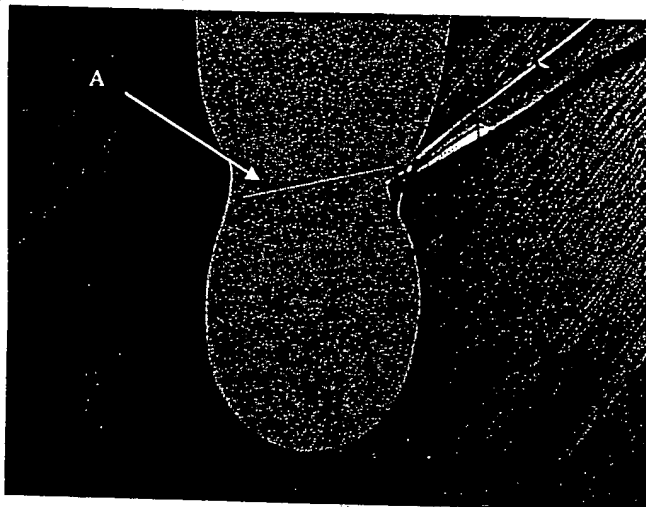
Part # 1999-10-14 Compression Spring  
Dimensions: 0.156" od x 0.106 id.  
Wire dia. 0.023"  
Thread pitch: 20 Threads per inch.  
Approx. 0.30 long  
10 total coils - 8 active  
Closed end - not ground  
Right hand thread  
304 S/S

*Prototype Parts done @ American Springs.*

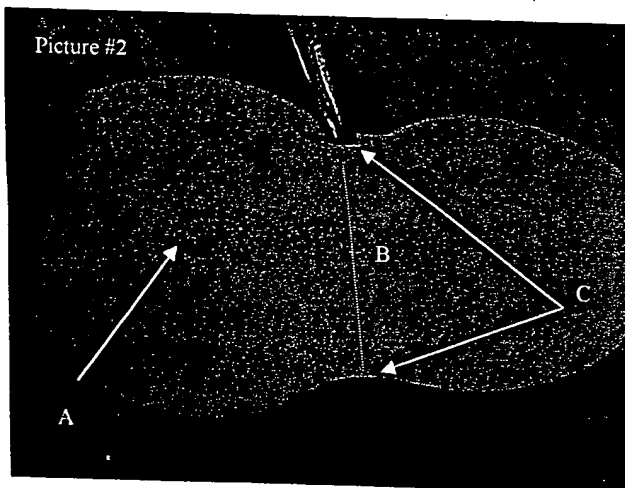
*GP-1*  
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*11-1-79*  
*11-1-79*

11-2-77

# Balloon Model to Illustrate Single Point Anchoring



Picture #2



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11-2-77

(Cont. PAGE 11)

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## Balloon model to illustrate Single Point Anchors.

### DESCRIPTION:

11-2-75

This balloon model was done to demonstrate the use of a single anchor through the left ventricle.

Picture #1 shows a thread penetrating through a latex balloon. Balloon was inflated and suture was restrained to maintain diameter.

Picture #2 illustrates pressurized chamber by squeezing the back end of the balloon. Thread length 'B' is maintained by hemostats. Diameter 'A' and overall length increases.

### NOTES:

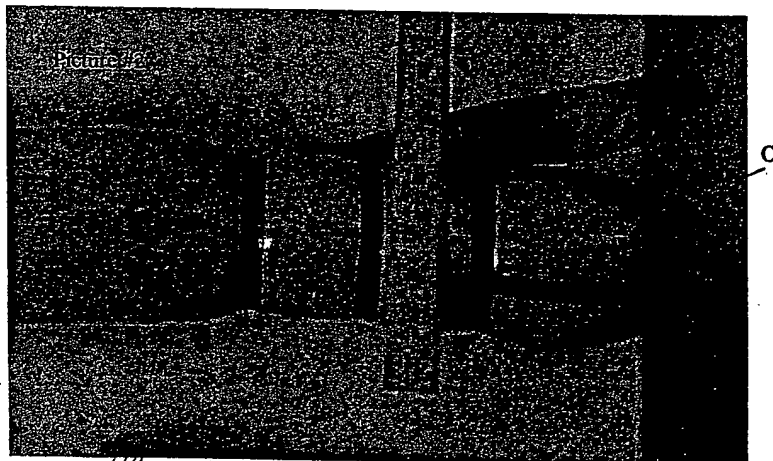
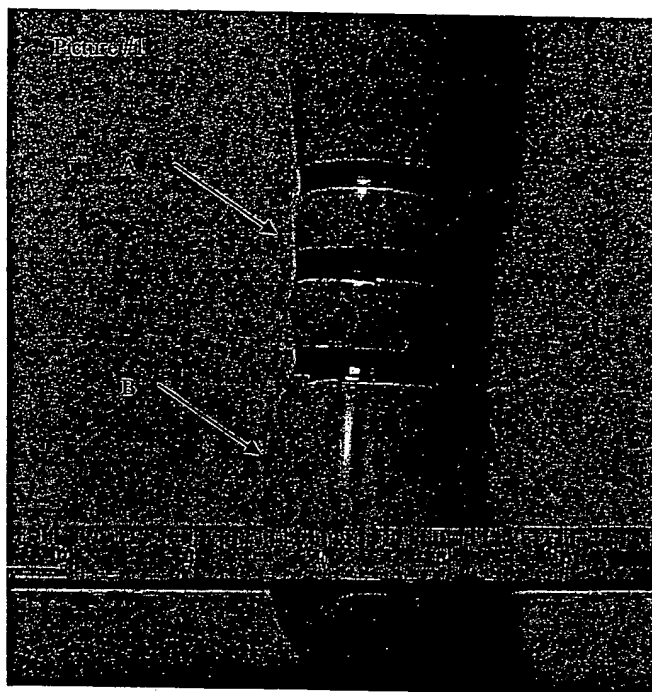
The use of a single or multiple anchors penetrating through the ventricle may not be advantageous as illustrated in Picture #2. Although diameter is maintained at the anchor, it appears that pressure is redistributed to weaker sections (A). Also, there may be increased point loading where the anchor penetrates the wall (C').

### Conclusion

This anchor method does not resist or restrain or expansion but limits the amount of extension in the wall. Chamber diameter is reduced at the anchor but pressure is redistributed to weaker areas. Multiple anchors may reduce overall wall stress but at the expense of more destructions in blood flow path.

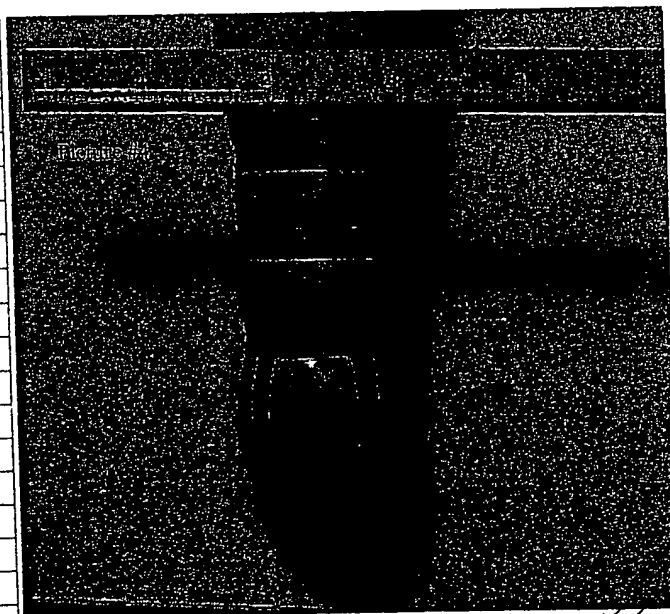
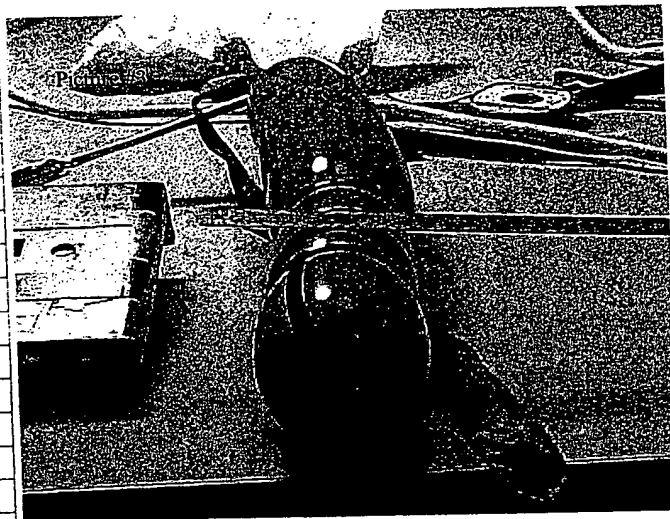
*[Handwritten signature and date 11-2-75]*

**Balloon Model to Illustrate affect of Anchoring Around Ventricle or Heart**



*Bill H. H. H.*  
11-2-99

(Cont. pg. 13)



*[Signature]*  
H-2-99.

(Cont. pg 14.)



#### Balloon Model to Illustrate Affect of Anchoring Around Ventricle or Heart

##### Description:

Congestive Heart Failure (CHF) is a condition caused by a failing heart and is associated to enlargement of the myocardium. The balloon models shown on pages 10-13 were done to illustrate the affects of different anchoring methods and ways to limit the diameter of the myocardium. The balloon model shown on page 12-13 was done to simulate the affects of wrapping bands around the inside of the ventricle or outside of the heart.

Picture #1 Illustrates multiple bands to limit diameter (A). Area B illustrates the affect of not limiting diameter. Since the diameter in the area around section A is limited, pressure is redistributed to weaker areas of the balloon causing the balloon to distend.

Picture #2 illustrates the affect of limiting distension along the long axis of the balloon by placing bands longitudinally. Pictures 3 and 4 illustrate expansion around the areas between the bands.

##### Conclusion:

The balloons used for the model were long and narrow. As the balloon was inflated, expansion occurred in two directions: radial and longitudinal. The anchoring methods shown demonstrated the ability to limit both expansion directions.

In an actual heart model, directional movements will be compound. Anchoring may have multiple configurations such as radial bands around the base of the heart and helical bands from the apex to the mid chamber. Current thinking is that from apex to mid chamber, muscle fibers are oriented in a helical direction and give the chamber a torsional movement. From mid chamber to the base, fiber orientation becomes more radial.

##### Materials:

Balloons - diameter approx. 1-1/2" x 3'

Electrical tape cut in widths approx. 1/8" strips

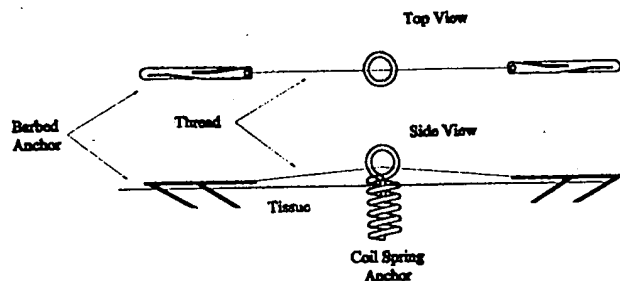
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11/3/79

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## END ANCHOR TERMINATION CONCEPTS.

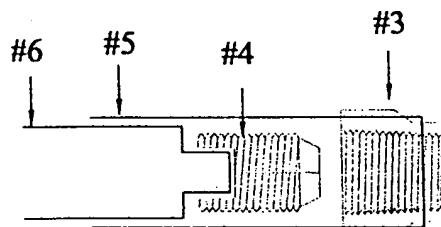
11-4-99.

#1



BH.

#2



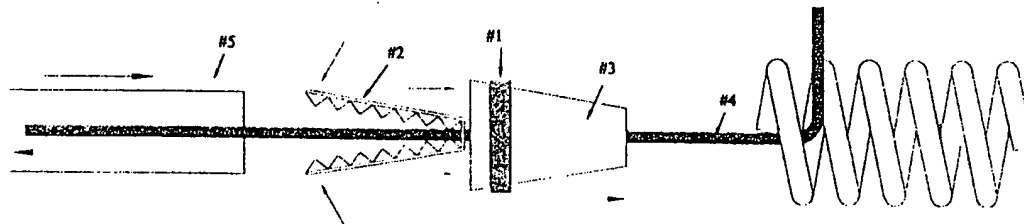
#1



#2

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#3



(CONT. 13-16) →

11/3/99

### End Anchor Termination Concepts

#### Description:

The current method for limiting heart and ventricle diameter is to place helical anchors into the pericardium, link them with a tether line and pull the anchors together to decrease or limit the overall diameter of the heart. Both the first and last anchors must be tied off in order to prevent the tether line from being pulled out of the anchor.

The drawings depicted on page 15 are end termination anchor concepts that would allow the tether line to be tensioned or released in order to choose the right end diameter of the heart.

Picture #1 shows both coil and barb anchors. Barbed anchors could be etched from stainless steel with eyelets to hold the tether line. Between the two, any number of coil anchors could be placed in order to distribute load. One or more of the coil anchors could be wound up to increase tension. If the position or tension was not ideal, springs could be unwound and repositioned.

Picture #2 illustrates a vise concept using coil springs. After placing the last anchor, the delivery device would be removed and the termination tool would be slid over the trailing tether line. Termination tool would consist of a collet (3), Vise (4), outer hypo-tube (5) and vise driver (6). Termination tool would be slid down to either mate with or be positioned along side of the coil spring. The collet would be held in the outer hypo-tube by wings or tabs in order to prevent the collet from sliding out and to prevent the collet from turning when the vise is engaged. As tension is applied to the thread (2), the vise would then be positioned and driven in by the vise driver (6) and in turn clamping the tether line. If the tether had to be released or re-tensioned, the outer hypo-tube could be repositioned and the process repeated.

Picture #3 depicts a similar method to number 2. This concept consist of a molded or machined serrated jaw (2) that is held in place by a collet (3). The assembly is held by a retaining band (1).

After deployment of the last anchor, the delivery device is removed and the termination tool is slid down the tether line. The collet (3) mates with the coil anchor. The serrated jaw is advanced with the driver (5) while tension is applied to the tether; jaw and collet would mate restraining the tether. If the termination had to be adjusted, the retaining band could be slid off the collet and the process repeated using either a new anchor or re-applying the retainer ring.

#### Conclusion:

Ideal termination of the anchors would allow the operator to re-adjust or re-position the end point. Termination could also be done by tying multiple knots around the last anchor. The disadvantage to knot tying would be the inability to adjust or reposition. The concepts depicted on page 15 allow for accurate placement as well as adjustments.

Also future revisions could be made to the tether line if slack were to develop by placing additional termination anchors within the band of existing anchors.

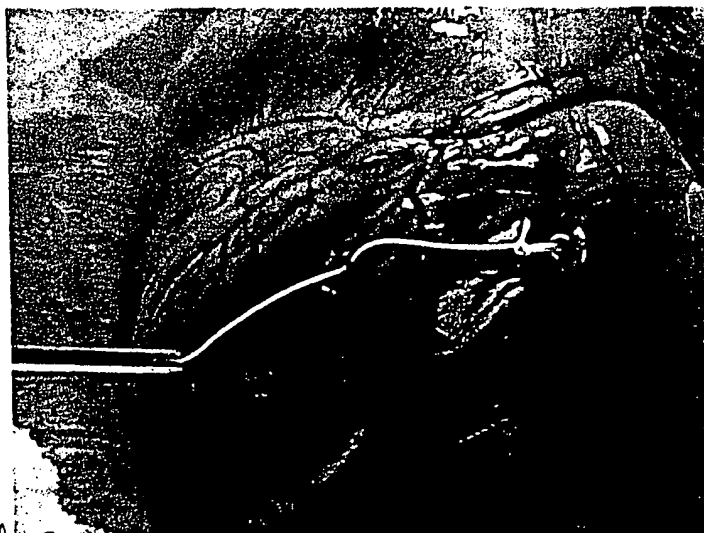
Parts could be either molded or machined.

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*[Signature]* 12/5/99

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## Anchor Deployment with Part # HA-1A



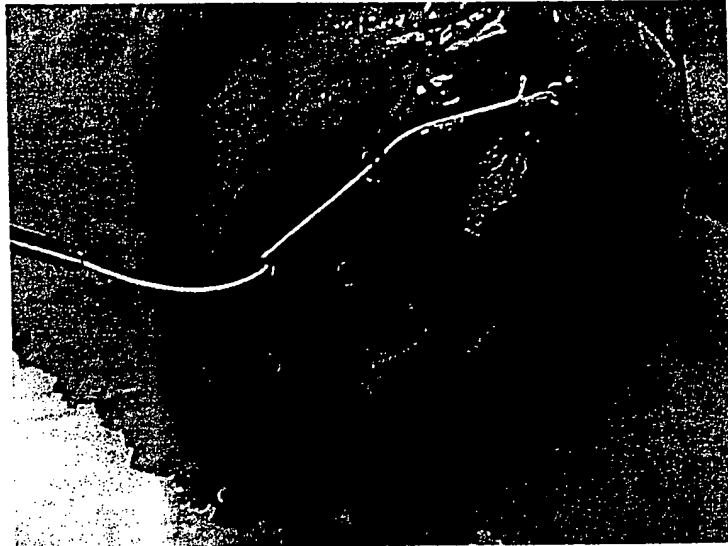
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(CONT PG 18) —D

11/4/99

## Anchor Deployment with Part # HA-1A



## Description:

Part # HA-1A

304 Stainless steel Hypo-tubing 0.134" od x 0.106" id  
0.020 bar width with 0.020 lasered slot.

Thread direction: left

After processing tube was stretched to render a thread pitch of approximately  
20 threads per inch.

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11-15-99

## In-Line Tether Springs 11/12/99

## Description:

Rather than passively restraining the epicardium as illustrated on pages 12, 13, and 14, the system could assist systemic contraction by placing a spring in-line with the anchors and tether line. During diastolic filling of the chamber, the springs would expand allowing the system to load as well as limit chamber diameter. During systole, the springs would recoil and assist in contraction. Springs could be flat, in plane with the heart, or they could be coiled as illustrated in Fig. 1 and 2. Entire tether and spring segment could also be encapsulated to prevent abrasion.

Fig 1

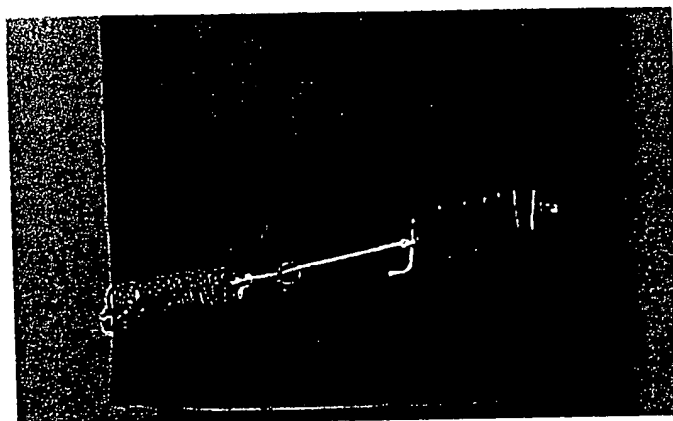
In-line Tether  
Springs

Top View

Tissue

Side View

Fig. 2



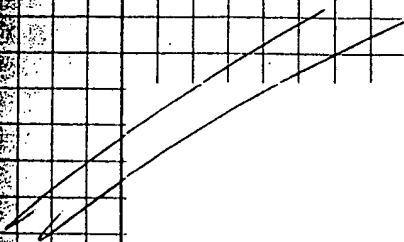
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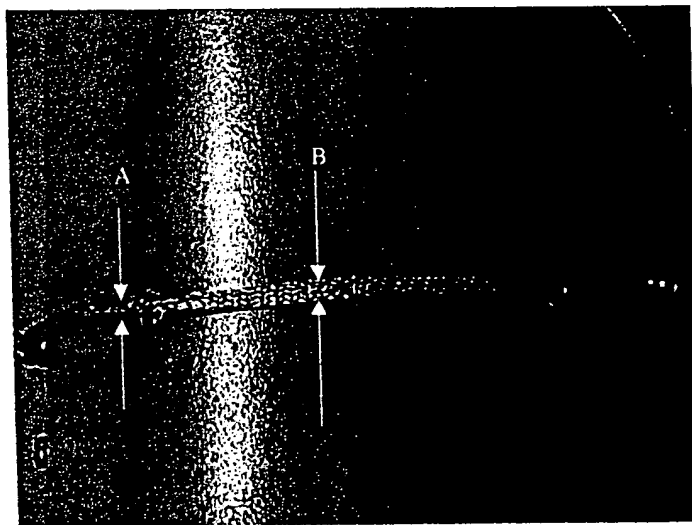
Tether Line Concept

**Tether Line Concept 11/15/99****Description:**

Tether line could be constructed out of a braid or weave to provide a wider contact area rather than a suture or similar line. By distributing the line over a greater width it may be less abrasive and stronger. Also the area where tether goes through the eyelet, the braid is able to compress as shown section A; section B remains original width. This is advantageous in order to minimize eyelet size.

Braid could be made from Dacron or similar fiber, braided metal or EPTFE.

Braid is illustrated using solder wick.



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11-16-99

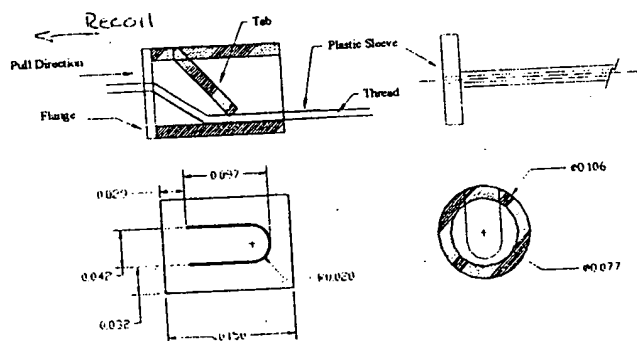
## End Termination Tether Line Clamp 11/16/99

## Description:

During the process of linking anchors to the epicardium it is necessary to terminate the tether line at the last anchor.

The drawing shown below is an End Termination Clamp concept. The clamp could be manufactured from Hypo-tubing with a slot cut through the wall as illustrated. Clamp could also contain a plastic sleeve to protect the suture or tether line when the tab is bent inward to pinch and lock the tether in position. Plastic sleeve could have serrations cut or molded in the tube to allow ratcheting and a positive lock as the sleeve and tether are pulled into the clamp. Sleeve could also have a flange as shown to prevent the tube from pulling through. Entire assembly could fit within the inside diameter of the coil anchor.

Tab could be pre-bent and slid down the tether to use as a onetime clamp, or a tool could be made that would allow the user to determine the best tension and then crimp the clamp closed. Tool could also undo the bent tab to allow for repositioning if results were not acceptable. Clamp could have multiple tabs to allow for multiple points of contact.



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11-16-99

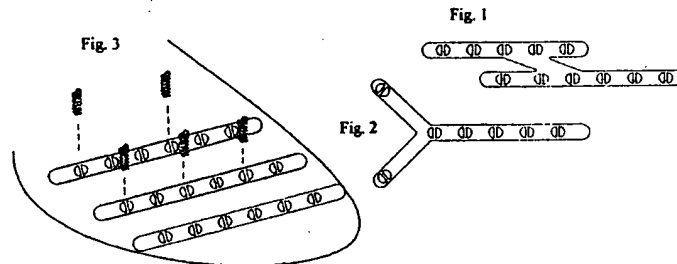
## Elastic Anchor Tether 11/16/99

## Description:

The picture below illustrates a method to tether between anchors in order to limit the amount of distension of the epicardium.

The tether would be made of a material such as silicon, rubber or polymer material having elastic properties.

Bands could be made in different configurations and lengths to allow for different elastic properties for the epicardium. For instance, fig 1 would apply a radial force as well as a longitudinal force depending on the angle of the connecting bar and the amount of tension applied. Fig. 2 would allow more initial anchor strength by providing two anchors perpendicular to each other; for possible placement on the septal wall. Fig 3 illustrates anchor positioning in order to increase or decrease the overall tension on the band at a given area of the heart.



## Method for placement:

After initial anchor was placed on the band and driven into the epicardium, the proceeding anchor would be placed in the desired hole location and a lateral force exerted on the anchor delivery device. This would cause the band to elongate and load. The location on the epicardium would then be chosen and the anchor delivered into the muscle. Remaining anchors would be delivered until the desired results were achieved.

## Notes:

The elastic bands may help systolic function by assisting ventricle contraction. During diastole, the chamber would fill with a limited amount of force being exerted by the bands. As the chamber ends diastolic filling, more force would be applied to the bands, in turn loading the system in order to assist during systole.

Bands could also have a radiopaque wire or markers imbedded in the polymer for two functions: Wire could serve as an overall limit so elastic band would not be able to expand beyond a given point, and markers could serve as a diagnostic function to monitor myocardial functions non-invasively.

Bands could be tensioned at a later procedure by anchoring into an un-used anchor hole, or bands could be cut at a later time after the myocardium had been restored to an optimal diameter.

## Advantage of elastic band over suture or single tether line:

- Force should be distributed equally to all anchors.
- No end termination is needed since the band would be placed and anchored as one unit.
- Connecting bar across anchor hole would work with existing anchors. As anchor was driven into the epicardium, connecting bar would be driven to the top of the anchor and stop in the anchor loop (Spring drawings pg. 6).
- Wider contact area between epicardium and tether.
- Assisted systolic function

11-17-99

# Elastic Tether 11/17/99

Fig. 1

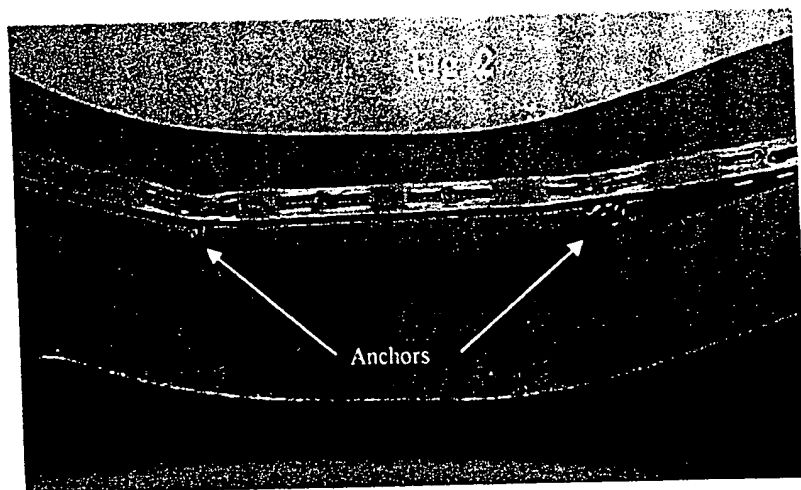
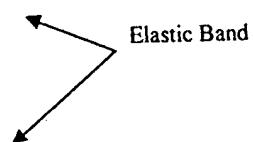
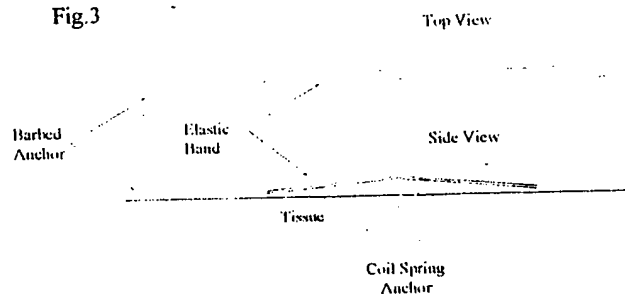


Fig. 3



*[Handwritten signature]*  
11-17-99

*[Handwritten signature]* 12/17/99

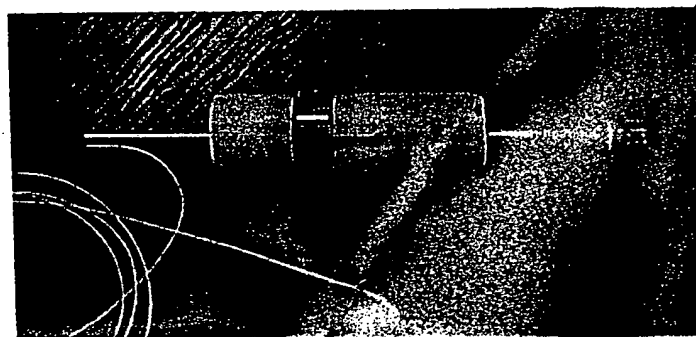
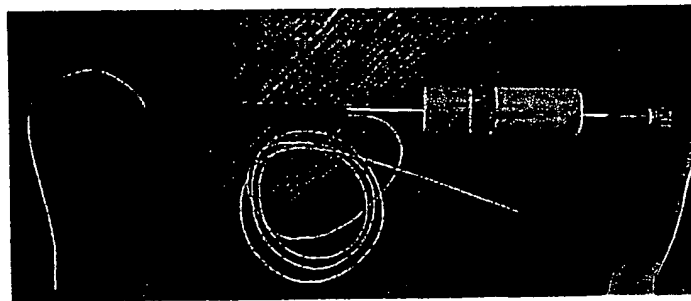
11/11/99

**Anchor Delivery Prototype 11/19/99****Description:**

The following pictures are a finished prototype of the delivery device drawing depicted on page 7.

The tether line is held along the side of the delivery tube with a 0.029"x 0.032" S/S hypo-tube and attached using 1/4" shrink tube. At the distal end of the delivery tube a 0.030" hole is drilled to receive the tether line. The hole penetrates one wall so that the tether line is forced into the lumen where the coil will pick up the line.

Notes: Revision of the device may use a larger delivery lumen so the tether line is able to be placed internally.



*B. H. H. H.*  
11-19-99

*R. M. H. H.* 12/15/99

11-24-99

## Ratchet Spooler (RS-01) 11/24/99

## Description:

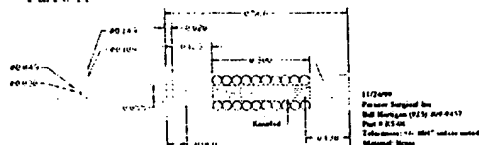
In the process of laying down anchors, it is necessary to terminate the tether line at the last anchor to prevent the line from being pulled out and loosing tension in the system; the drawing below depicts a method to terminate the tether line.

Part #A is the center mandrel. Tether is taken up through the anchor and fed through the center of the mandrel. Line exits on the center diameter as shown in Part C.

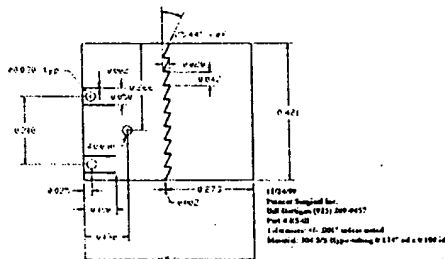
Part B is a ratchet which allows slack to be taken out of the line and maintains tension with the interlocking teeth. Half of the section is fixed to the mandrel, the other end is allowed to rotate. As the ratcheting tool is turned, slack is taken up and wound on the mandrel. Teeth are installed to be directional in that they allow the tether to be taken up but not unwound.

Part C shows the entire assembly with the thread wrapped on the mandrel. Parts will be fabricated from 0.134"od x 0.109"id S/S hypo-tubing. Mandrel will be made from brass.

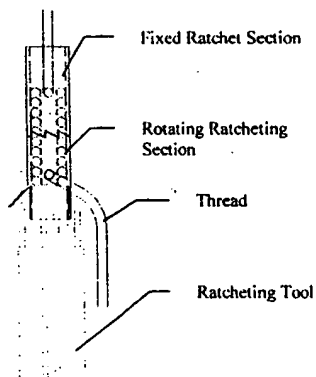
Part # A



Part # B

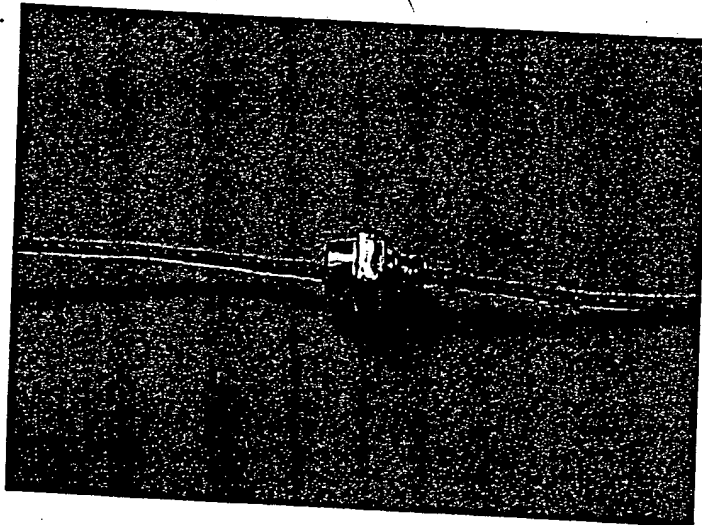
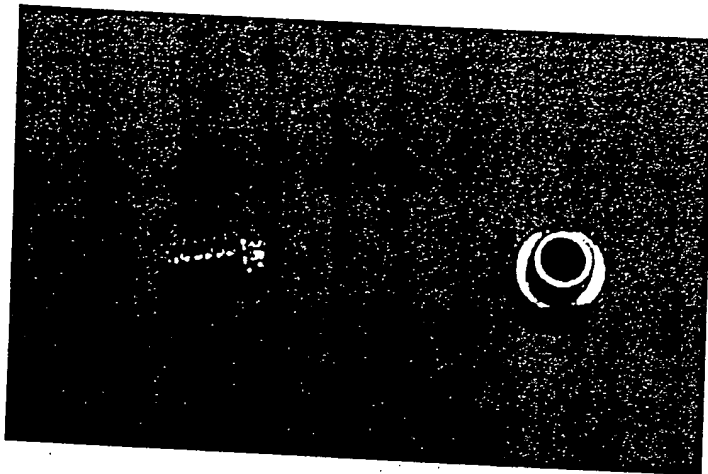


Part # C



Norma M. Velez 12/15/99

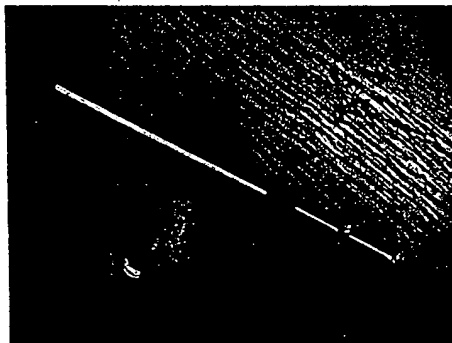
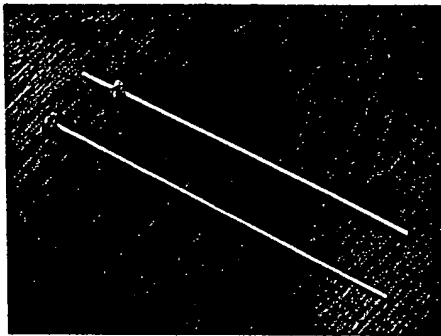
Prototype of End Termination Anchor 12/2/99



cont. P6 07528

Donna V. Neale  
12/15/99

## Anchor Termination - Pin Vise Method 12/9/1999



*Donna M. Heath*  
12/15/99

*Donna M. Heath*  
12/15/99

*Donna M. Heath*  
12/15/99

## Pin Vise Tether Line Concept 12/3/99

## Description:

The pictures shown on page 26, 27 and these drawings, depict a tether line termination concept. With the current method of harnessing and anchor deployment, it is necessary to terminate the tether line at the last anchor. Ideally, the termination would be adjustable and removable. The termination should also be low profile so it would not interfere with surrounding tissue. The miniature pin vise shown below is a method for termination which would satisfy those requirements.

## Method:

After the last anchor is deployed, the anchor delivery tool is removed leaving the remaining tether line. The tether line is passed through the pin vise assembly (collet, and vise) and the two halves are threaded together. Next the tightening tool (pg 27) is advanced over the tether until it mates with the vise. The assembly is slid into position with the smaller diameter of the collet nesting into the inner diameter of the coil anchor. The assembly is tightened up by applying tension to the tether line. The knurled knob on the outer hypo-tube is held in place; this engages the outer hex on the collet section. Lastly the inner hypo-tube which engages the back-end of the vise section is rotated thereby closing the jaws around the tether line. If tension was not sufficient, the vise could be loosened or removed and reapplied to get the desired results. Lastly, the tether line is trimmed off to the desired length.

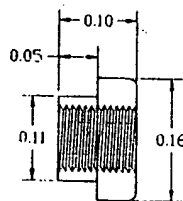


Fig. 1

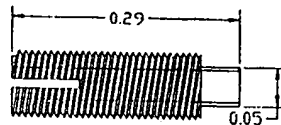


Fig. 2

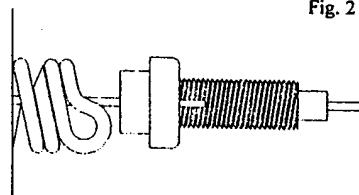
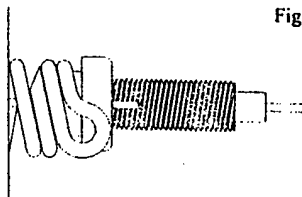


Fig. 3



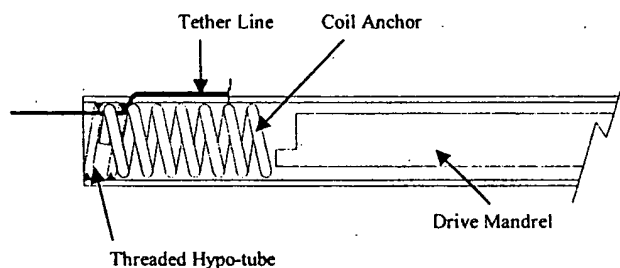
12/15/99

### Tether Line Pick-up Concept for Delivery Tool 12/14/99

#### Description:

During the delivery of the coil springs it is necessary to link the anchors together using a tether line. The problem with integrating the tether and anchor together is reliably picking up the tether so that it is allowed to wind up on the inside of the coil. If the tether line is simply allowed to go through the wall of the hypo-tube, depending on orientation of the tether, the coil anchor is likely to pin the line against the wall of the tube and miss the line. The picture below illustrates a method to pick up the line regardless of the orientation of the tether.

Tether line pick up would be done by threading the inside diameter of the delivery tool hypo-tube shown in red. The tether line could be run along the outside of the tool and then directed to the inside by drilling a hole through the hypo-tube (shown in solid blue). The tether line would then be placed over the hypo-tube threads so that as the coil anchor is advanced and threaded into the tissue the tether line would automatically be picked up. Orientation of the tether line would not matter so long as it is resting over the top of the hypo-tube threads.



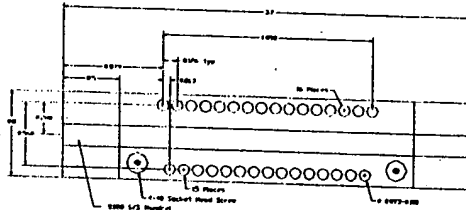
*[Signature]*  
12/15/99

*[Signature]* 12/15/99



# Stand-off Fixture 12/10/99

**Description:** The following drawings and pictures are a method to support the tether line between anchors so that the line does not abrade or cut the tissue.



The pictures on the following page are completed prototypes of the standoffs. Fig. 1 is the complete fixture wound with .008" niti wire. Fig. 2 is the completed stand off after heat setting. Figs. 3 and 4 demonstrate a method of deployment and the tether line within the standoff. Deployment would be done using either the single shot or the multi shot delivery method (pg 2-3 and pg 7 and 24). Not shown is the method to advance the standoffs. A likely method would be a co-axial design. Standoffs would be loaded over the delivery tool and captured in a larger hypo tube. Between the two tubes would be a smaller tube to push the standoffs out. Parts could be advanced as needed by pushing a smaller diameter hypo tube thus releasing the standoff. Delivery of the standoffs would be independent of the anchors and would not interfere. The co-axial design would be a benefit in that the tether line would automatically be centered in the standoff as it was deployed. Fig. 5 is a different method of winding. The standoff in fig. 2 must be laid down with the legs against the tissue in order to be affective. The standoff shown in fig. 5 was wound so that orientation does not matter. If the standoff was flipped upside down every other leg would make contact with the tissue.

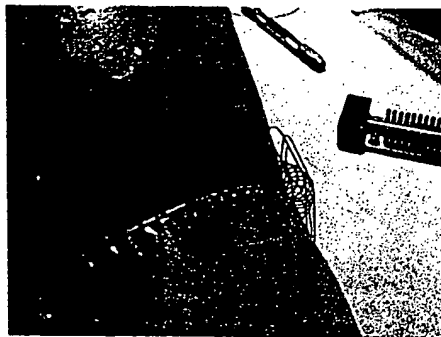
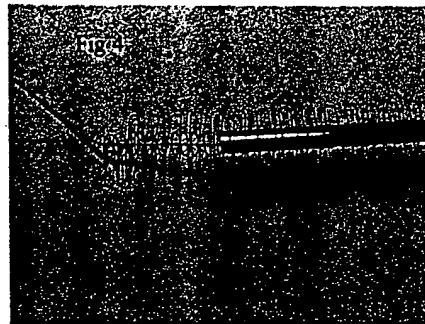
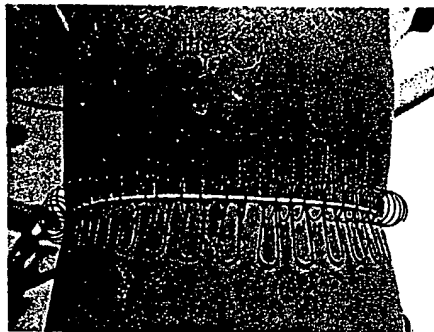
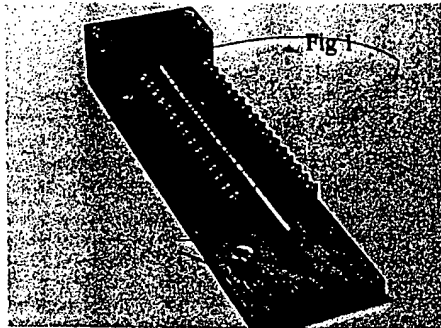
## Conclusion:

Standoffs could be cut to any length and different wire diameters to allow for different stiffness or different lengths between anchors.

*[Signature]*  
12/15/99

*[Signature]* 12/15/99

## Stand-off Fixture and Prototypes 12/9/99



Robert McNamee 12/15/99

B. H. H. 12/15/99

### Anchor Delivery Method 12/9/99

The following pictures are a sequence of photographs depicting the current method of anchor and tether line deployment used to harness the epicardium. The deployment was done using a pig heart on the bench.

#### Pictures:

Fig. 1 is the single shot anchor deployment tool. Coil anchors are placed into the lumen of the tool and the tether line attached to the first anchor with a knot and loop (fig 2). Up to three anchors may be placed in the lumen. Subsequent anchors pick up the tether line automatically as it is threaded down the center of the deployment tool lumen.

Next the tool is placed on the epicardium and the anchor deployed by turning the knurled knob on the delivery tool (fig 3 and 4). As the anchor is advanced, the tether is threaded to the top until it is captured at the very end of the coil.

Figs. 5 and 6 show a stand-off being placed in order to minimize the tether line contact with the tissue. The stand-off is flexible both longitudinally and laterally, and offers a wide foot print to distribute the load of the line.

Fig. 7 and 8 are continuations of anchor and standoff placement.

Fig 9 and 10 show the pin vise end termination method. The tether line is passed through both the vise and collet section and advanced down to the spring using the tightening tool (fig 11). The vise is placed so that the smaller diameter of the collet nests within the coil.

A scale was placed along the system to show the start dimension prior to tensioning (fig 12). Fig 13 shows tension being applied to the tether line and the change in dimension. Next, the pin vise was tightened and the tool removed.

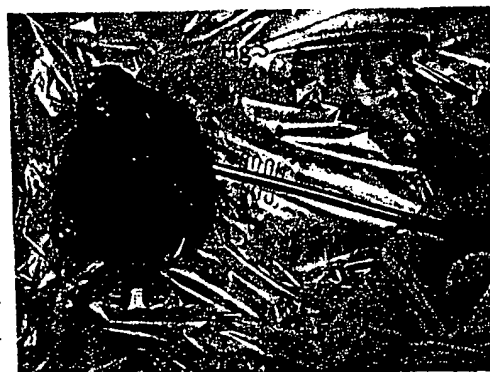
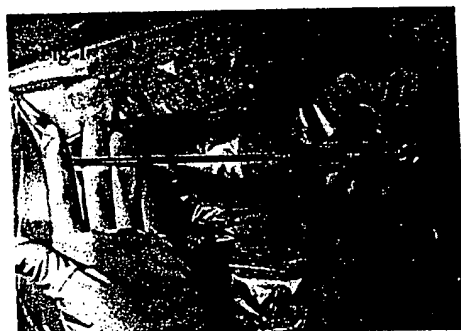
Fig. 14 and 15 show the end results using 2 standoffs, 3 coil anchors, tether line and end termination pin vise.

Cont. Pg. 33, 34 & 35

*[Signature]*  
12/15/99

*[Signature]* 12/15/99

## Anchor Delivery Method 12/9/99



Bill Hays  
12/15/99

Donna McLeod 12/15/99

Anchor Delivery Method 12/9/99



Fig 7



Fig 8

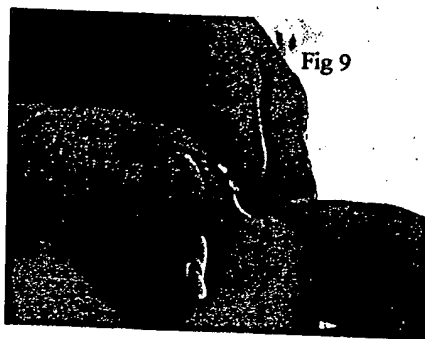


Fig 9



Fig 10

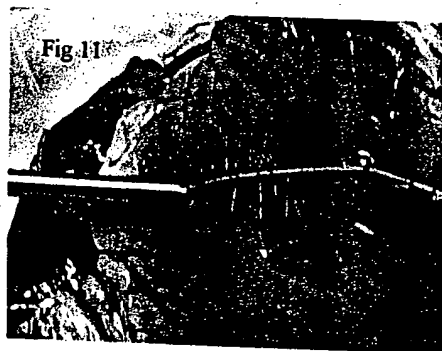


Fig 11

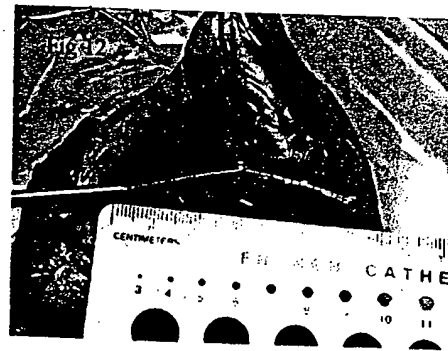
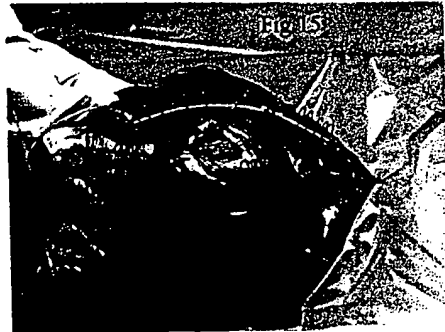
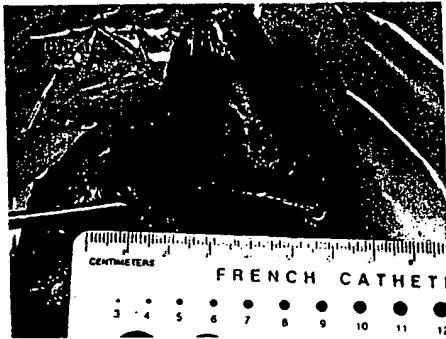


Fig 12

*Dr. [Signature]*  
12/10/99

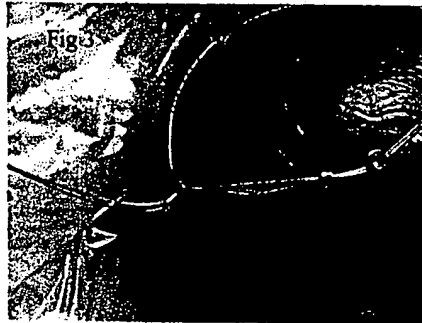
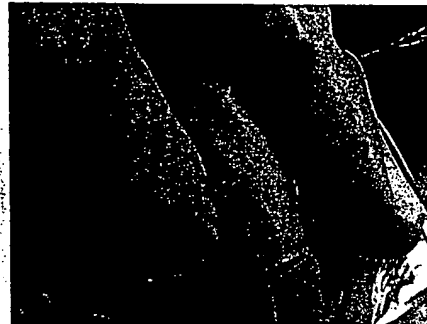
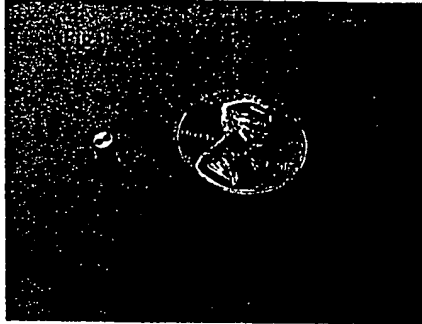
*Norman M. [Signature]* 12/15/99

## Anchor Delivery Method 12/9/99



*Bill Harty*  
12/15/99  
*Deanna M. Harty*  
12/15/99

## Anchor Termination - Tether Tie-off Method 12/9/1999



*Bob Harty*

## Anchor Termination - Tether Tie-off Method 12/9/99

The pictures above depict another method of terminating the tether line at the last anchor. This concept is a simple plug with two holes drilled through it's length. (fig. 1). This Termination would be used with two independent parallel lines which would offer added security in the event one line were to break.

## Method:

The two tether lines are passed through the two holes in the plug (Fig 2). Tension would be applied by pulling on the tether line while fixing the plug within the coil anchor by means of a hemostat or similar tool. Once the desired tension was applied, the hemostat would clamp the line at the top of the plug fixing position: a common surgical knot could be slid down the tether securing the tether (fig 3).

*Bob Harty*  
12/15/99

*Romana M. Harty*  
12/15/99

### Anchor Termination - Ratchet Prototype 12/9/99

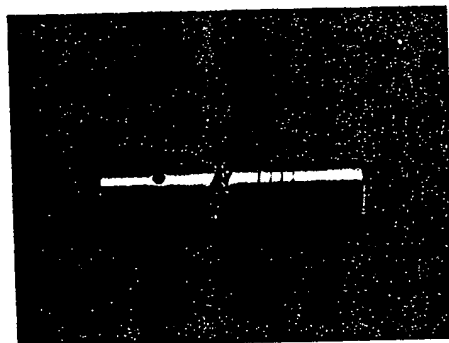
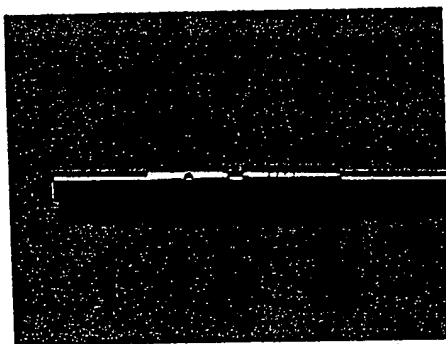
The following pictures are a continuation of the drawings shown on page 25. This is a finished prototype of part "B". A coil section was added that was not shown in the drawing. This spring will allow the teeth to unlock and rotate to take up slack but springing back and locking the position when the ratcheting tool is removed. This part was not completed due partly because of the size of the device and because of a more reliable pin vise anchor shown on pages 26 and 27. This part may be continued at a later time.

#### Materials:

316 S/S Hypo-tube 0.109" ID x 0.134" OD  
Part # RS-01

*Bill Harty*  
12/15/99

### Ratchet End Termination Concept 12/9/99



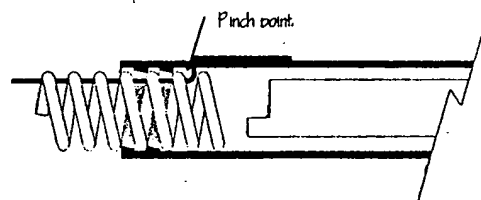
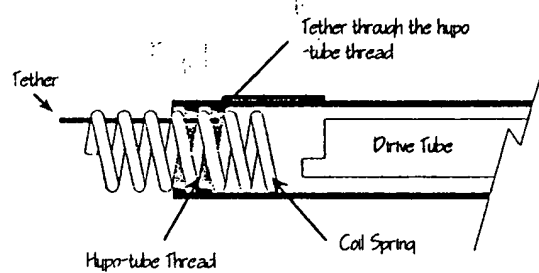
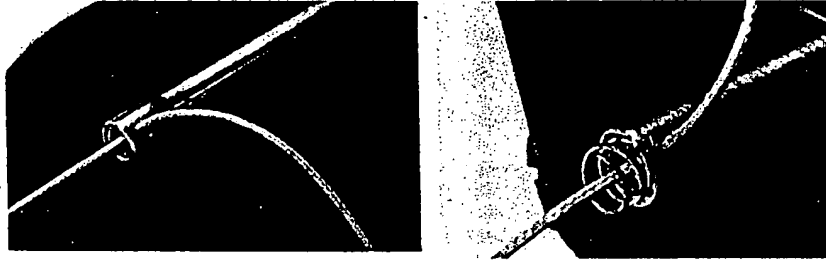
*Bill Harty*  
12/15/99

*Donna M. Harty*  
12/15/99



## Tether Line Pick-up Prototype 12/17/99

Description: The following pictures and drawings are a continuation of the concept shown on page 29.



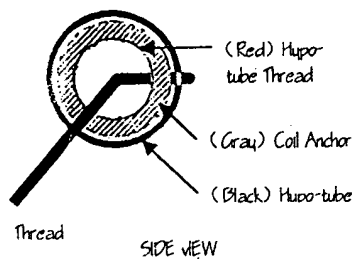
Two holes were drilled in the hypo-tube; one in back of the last thread and the other through the hypo-tube thread. Threads take up approximately 0.060" of the distal end of the hypo-tube and revolve slightly more than one revolution of thread. Thread spacing is the same pitch as the anchor at 20 threads per inch. For this prototype, the hypo-tube thread was made of brass and welded into the inner diameter of the tube.

Continued Pg. 39.

# Tether Line Pick-up Prototype 12/17/99 (Continued)

## Method:

The tether line is threaded through the hole in the hypo-tube. The first anchor could be attached to the tether line with a loop; proceeding anchors would automatically pick up the tether line regardless of the orientation of the thread as shown in the end view of the delivery tool below.



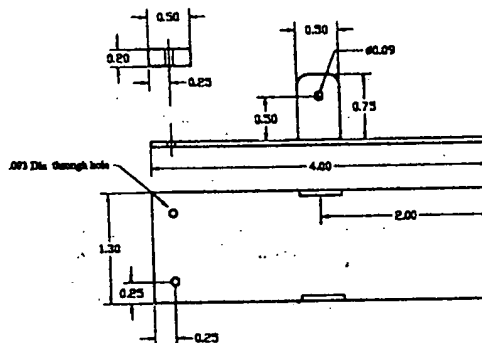
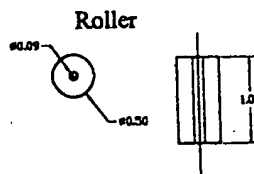
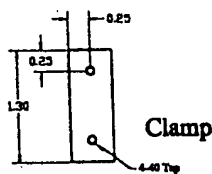
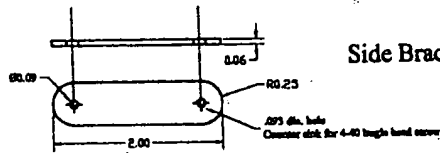
## Notes:

- Drive shaft would not need to be threaded as with previous drawings of the single shot or multi shot pm-1 since the hypo-tube thread would be the guide to drive the anchor. This system could be used with either single or multi shot drive mechanism.
- The benefit of drilling through the hypo-tube thread is that as the anchor is threaded, the tether line will not come in contact with the leading point of the anchor as shown in Fig. 1. Fig. 2 depicts the disadvantage of drilling the hole beyond the hypo-tube thread. Potentially the thread could become lodged behind the anchor or the tip of the anchor could barb through the tether line. The tether could also become pinched between the hypo-tube thread and the anchor.
- Different anchor configurations could be loaded as needed; thread pickup would not be dependent on the type of anchor used.
- Tether line could be run either on the or outside of the hypo-tube.

*[Handwritten signature]*  
12/17/99

*[Handwritten signature]*  
12/17/99

Drawings for Muscle Attachment Clamp 01/31/00



Paracor Surgical, Inc.  
Bill Hartigan  
1/27/00  
Muscle Attachment Clamp

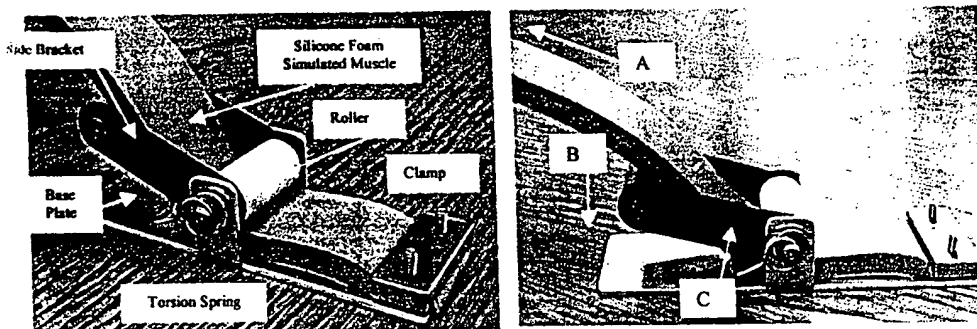
*[Signature]*  
1-31-00

*[Signature]*  
1/31/00

Continued next Page

01-31-00

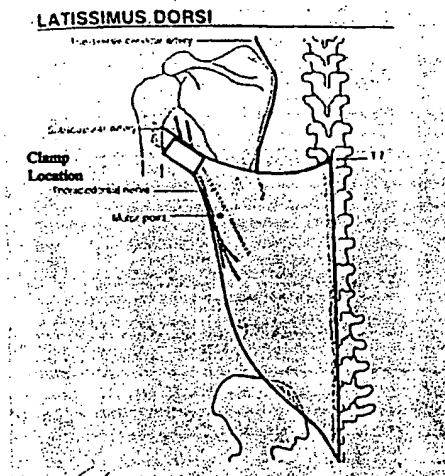
### Prototype Muscle Attachment Clamp 01/31/00



#### Description:

The above pictures are a prototype of a muscle attachment concept that would be used to drive a cardiac harness. The clamp could be attached to the Latissimus Dorsi by removing the side bracket and placing the muscle over the roller assembly (as illustrated by the silicone foam). This could potentially leave the muscle intact not having to remove the attachment at the humerus. The base plate could then be anchored to a fixed position such as the rib cage or other bone structure.

The muscle could be paced in order to coincide with the contractions of the left ventricle. As the muscle was tensioned (A) it would exert a downward movement on the clamp assembly thereby pushing or pulling a cable that could be attached to the side bracket of the assembly (B). The movement could be translated to a harness attached to the heart; actively assisting the contractile function. The torsional spring would help the system recoil (C).



Dr. H. H. H. H.  
01-31-00

01-31-00

**Paracor Surgical, Inc.**

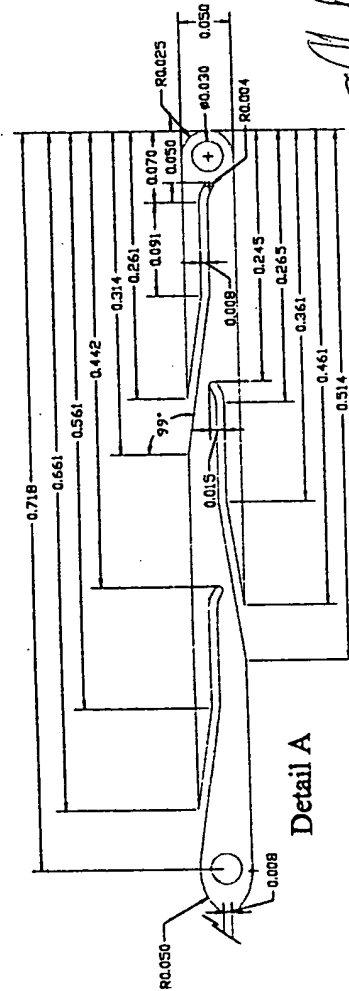
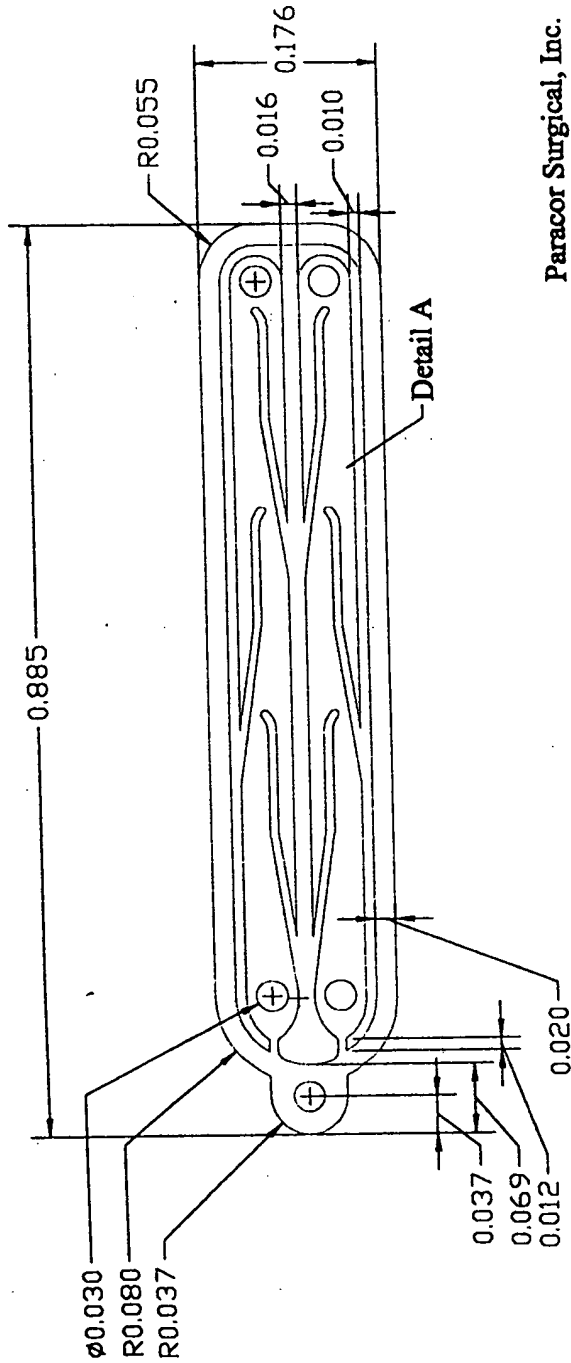
02/14/00

Bill Hartigan (925) 209-9457


**Material: 316 S/S**

Thickness: 0.008"

**Tolerances:  $\pm 0.001$ " unless noted**



2/14/00



43  
3/2/00

The following attached cards (Pg 43-44) were used to prototype wire cages.



**SHAPE MEMORY  
APPLICATIONS, INC.**  
2380 OWEN STREET  
SANTA CLARA, CA 95054  
PHONE (408) 727-2221  
FAX (408) 727-2778  
WWW.SHAPE-APP-INC.COM

**Certificate of Conformance**

SMA Certification Number: 4604  
Certification Date: March 1, 2000

Customer: Paracor Surgical  
P.O.#: 3027

SMA Work Order #: 9511

**PRODUCT AND MATERIAL INFORMATION**

**PRODUCT AND MATERIAL INFORMATION**

**Description:** NiTi Wire, 0.0263" nominal diameter, Superelastic, Alloy 5, As Drawn, Oxide Surface

Part # / Rev.:  
Quantity: 235 ft.  
Alloy: S

Manufacturing Lot #: 9511  
Inventory Control #: SCF0156  
Raw Material Lot #: RM0095

## MECHANICAL AND PHYSICAL PROPERTIES

Condition:	As Drawn
Surface:	Oxide
Ingot A <sub>g</sub> :	6°C

UTS (ksi):	205
Elongation (%):	15
Active A <sub>1</sub> (°C):	

**CHEMICAL COMPOSITION (WEIGHT %)**

CHEMICAL COMPOSITION (WEIGHT %)					
NI	TI	C	O	H	Total All Others
55.90	43.92	.044	.058	.0019	.0761

**ADDITIONAL REQUIREMENTS/NOTES**

This material will meet customer specifications and shall be free of lubricants, chips, dirt, debris. Shape Memory Applications, Inc. does not warrant against any damage arising from the use of this product, or any other damage contingent or otherwise which might arise in connection with this product.

**Signature**

O.A. Approval This No

Date 2/1/2023

Customer Copy

Read +  
UNDERSTOOD 57

(cont - 2)

Sma NiTi Cert.

3/2/00



SHAPE MEMORY  
APPLICATIONS, INC.  
1380 OWEN STREET  
SANTA CLARA, CA 95054  
PHONE (408) 727-2211  
FAX (408) 727-2779  
http://www.sma-inc.com

## Certificate of Conformance

SMA Certification Number: 4549

Certification Date: February 23, 2000

Customer: Paracor Surgical  
P.O.#: 8062

SMA Work Order #: 9457

## PRODUCT AND MATERIAL INFORMATION

Description: NiTi, Wire, 0.005" diam.  $\pm 0.0002$ , Superelastic, Alloy N, As Drawn, Oxide Surface

Part # / Rev.:  
Quantity: 1500 ft.  
Alloy: N

Manufacturing Lot #: 9457  
Inventory Control #: NCT0273  
Raw Material Lot #: RMU301

## MECHANICAL AND PHYSICAL PROPERTIES

Condition:	As Drawn	UTS (ksi):	264
Surface:	Oxide	Elongation (%):	6.1
Ingot A <sub>1</sub> :	-18°C	Active A <sub>1</sub> (°C):	

## CHEMICAL COMPOSITION (WEIGHT %)

Ni	Ti	C	O	Total All Others
55.73	Bal	≤ .05	≤ .05	≤ .20

## ADDITIONAL REQUIREMENTS/NOTES

This material will meet customer specifications and shall be free of lubricants, chips, dirt, debris.  
Shape Memory Applications, Inc. does not warrant against any damage arising from the use of this product, or any other damage contingent or otherwise which might arise in connection with this product.

Signature: *[Signature]*  
Q.A. Approval Thu Ho

Date: 2/23/2000

Customer Copy

*[Signature]*  
3/2/00

*[Signature]*  
4/12/00  
(Cont - 2)

45

SMA N.Ti Ckt

3/2/00



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APPLICATIONS, INC.  
2300 OWEN STREET  
SANTA CLARA, CA 95054  
PHONE (408) 737-2221  
FAX (408) 737-2178  
http://www.sma-inc.com

# Certificate of Conformance

SMA Certification Number: 4550

Certification Date: February 23, 2000

Customer: Paracor Surgical  
P.O.#: 8062

SMA Work Order #: 9459

## PRODUCT AND MATERIAL INFORMATION

Description: NiTi, Wire, 0.010" diam.  $\pm 0.0003$ , Superelastic, Alloy N, As Drawn, Oxide Surface

Part # / Rev.:  
Quantity: 675 ft.  
Alloy: N

Manufacturing Lot #: 9459  
Inventory Control #: NCT0306  
Raw Material Lot #: RM0301

## MECHANICAL AND PHYSICAL PROPERTIES

Condition: As Drawn  
Surface: Oxide  
Ingot A<sub>1</sub>: -18°C

UTS (ksi): 286  
Elongation (%): 6.4  
Active A<sub>1</sub> (°C):

## CHEMICAL COMPOSITION (WEIGHT %)

Ni	Ti	C	O	Total All Others
55.73	Bal	$\leq .05$	$\leq .05$	$\leq .20$

## ADDITIONAL REQUIREMENTS/NOTES

This material will meet customer specifications and shall be free of lubricants, chips, dirt, debris.  
Shape Memory Applications, Inc. does not warrant against any damage arising from the use of this  
product, or any other damage contingent or otherwise which might arise in connection with this product.

Signature

Q.A. Approval The No

Date

2/23/2000

Customer Copy

*[Signature]*  
3/2/00

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(cont. ->) *[Signature]*  
4-TC-00



Sma: N Ti Cert

3/2/00



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SANTA CLARA, CA 95054  
PHONE (408) 727-2221  
FAX (408) 727-2778  
http://www.sma-inc.com/

## Certificate of Conformance

SMA Certification Number: 4551

Certification Date: February 23, 2000

Customer: Paracor Surgical  
P.O.#: 8062

SMA Work Order #: 9458

## PRODUCT AND MATERIAL INFORMATION

Description: NITICr, Wire, 0.008" diam.  $\pm 0.0003$ , Superelastic, Alloy C, As Drawn, Oxide Surface

Part # / Rev.:

Quantity: 790 ft.

Alloy: C

Manufacturing Lot #: 9458

Inventory Control #: CCS2503

Raw Material Lot #: RM0872

## MECHANICAL AND PHYSICAL PROPERTIES

Condition: As Drawn

Surface: Oxide

Ingot A<sub>1</sub>: -11°C

UTS (ksi): 266

Elongation (%): 7.0

Active A<sub>1</sub> (°C):

## CHEMICAL COMPOSITION (WEIGHT %)

NI	TI	C	O	Total All Others
55.73	44.04	≤ .05	≤ .05	≤ .20

All Others Are: Al, Co, Cu, Fe, Mn, Mo, Nb, Si, W

## ADDITIONAL REQUIREMENTS/NOTES

This material will meet customer specifications and shall be free of lubricants, chips, dirt, debris.  
Shape Memory Applications, Inc. does not warrant against any damage arising from the use of this  
product, or any other damage contingent or otherwise which might arise in connection with this product.

Signature

Q.A. Approval This No

Date 2/23/00

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*[Signature]*  
3/2/00

(CONT -&gt;)

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*[Signature]* 4/2/00

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3/2/00



SHAPE MEMORY  
APPLICATIONS, INC.  
2380 OWEN STREET  
SANTA CLARA, CA 95054  
PHONE (408) 727-7221  
FAX (408) 727-3770  
http://www.sma-inc.com

# Certificate of Conformance

SMA Certification Number: 4552

Certification Date: February 23, 2000

Customer: Paracor Surgical  
P.O.#: 8062

SMA Work Order #: 9461

## PRODUCT AND MATERIAL INFORMATION

Description: NiTi Wire, 0.0193" diam.  $\pm 0.0004$ , Superelastic, Alloy 5, As Drawn, Oxide Surface

Part # / Rev.:

Quantity: 350 ft.

Alloy: S

Manufacturing Lot #: 9461

Inventory Control #: SCT0955

Raw Material Lot #: RM0314

## MECHANICAL AND PHYSICAL PROPERTIES

Condition: As Drawn

Surface: Oxide

Ingot A<sub>1</sub>: -4°C

UTS (ksi): 230

Elongation (%): 11

Active A<sub>1</sub> (°C):

## CHEMICAL COMPOSITION (WEIGHT %)

NI	TI	C	O	Total All Others
56.04	Bal	$\leq .05$	$\leq .05$	$\leq .20$

## ADDITIONAL REQUIREMENTS/NOTES

This material will meet customer specifications and shall be free of lubricants, chips, dirt, debris.  
Shape Memory Applications, Inc. does not warrant against any damage arising from the use of this  
product, or any other damage contingent or otherwise which might arise in connection with this product.

Signature

Q.A. Approval Thu No

Date

2/23/2000

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*[Signature]*  
3/2/00

(CONF. - 2)

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*[Signature]*  
4/2/00

SMA NITi Cert 2/2/00



SHAPE MEMORY  
APPLICATIONS, INC.  
2380 OWEN STREET  
SANTA CLARA, CA 95054  
PHONE (408) 737-2221  
FAX (408) 737-3776  
WEB: [www.sma-inc.com/](http://www.sma-inc.com/)

## Certificate of Conformance

SMA Certification Number: 4548

Certification Date: February 23, 2000

Customer: Paracor Surgical  
P.O.#: 8062

SMA Work Order #: 9460

## PRODUCT AND MATERIAL INFORMATION

Description: NITiCr Wire, 0.0153" diam.  $\pm 0.0004$ , Superelastic, Alloy C, As Drawn, Oxide Surface

Part # / Rev.:

Quantity: 465 ft.

Alloy: C

Manufacturing Lot #: 9460

Inventory Control #: CCS1253

Raw Material Lot #: RM0392

## MECHANICAL AND PHYSICAL PROPERTIES

Condition: As Drawn

Surface: Oxide

Ingot A<sub>1</sub>: -14°C

UTS (ksi): 230

Elongation (%): 7.6

Active A<sub>1</sub> (°C):

## CHEMICAL COMPOSITION (WEIGHT %)

NI	TI	Fe	C	O	Total All Others
55.68	44.14	≤ .05	≤ .05	≤ .20	≤ .20

All Others Are: Al, Co, Cu, Fe, Mn, Mo, Nb, Si, W

## ADDITIONAL REQUIREMENTS/NOTES

This material will meet customer specifications and shall be free of lubricants, chips, dirt, debris.  
Shape Memory Applications, Inc. does not warrant against any damage arising from the use of this  
product, or any other damage contingent or otherwise which might arise in connection with this product.

Signature

Q.A. Approval Thu Ho

Date

2/23/2000

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3/1/00



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FAX (408) 737-2779  
http://www.sma-inc.com

# Certificate of Conformance

SMA Certification Number: 4557

Certification Date: February 23, 2000

Customer: Paracor Surgical  
P.O.#: 8062

SMA Work Order #: 9471

## PRODUCT AND MATERIAL INFORMATION

Description: NiTiCr, Wire, 0.032" diam.  $\pm 0.0005$ , Superelastic, Alloy C, As Drawn, Oxide Surface

Part # / Rev.:  
Quantity: 170 ft.  
Alloy: C

Manufacturing Lot #: 9471  
Inventory Control #: CCS3163  
Raw Material Lot #: RM0634

## MECHANICAL AND PHYSICAL PROPERTIES

Condition:	As Drawn	UTS (ksi):	244
Surface:	Oxide	Elongation (%):	7.2
Ingot A <sub>1</sub> :	-10°C	Active A <sub>1</sub> (°C):	

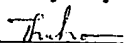
## CHEMICAL COMPOSITION (WEIGHT %)

Ni	Ti	Cr	C	O	Total All Others
55.65	44.09	.25	≤ .05	≤ .05	≤ .20

All Others Are: Al, Co, Cu, Fe, Mn, Mo, Nb, Si, W

## ADDITIONAL REQUIREMENTS/NOTES

This material will meet customer specifications and shall be free of lubricants, chips, dirt, debris.  
Shape Memory Applications, Inc. does not warrant against any damage arising from the use of this  
product, or any other damage contingent or otherwise which might arise in connection with this product.

Signature:   
Q.A. Approval Thu Ho

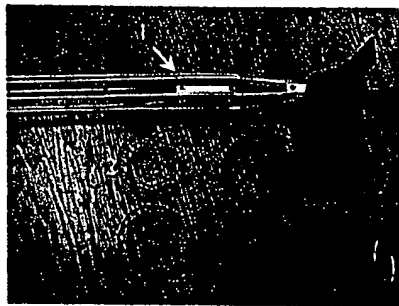
Date: 2/23/2000

Customer Copy

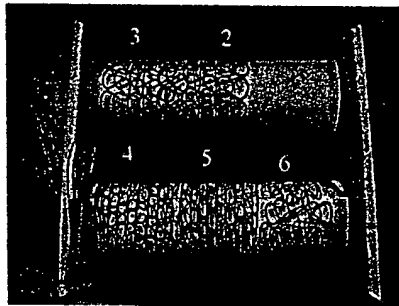
W.H. White  
3/1/00

3/10/00

Devices Sent to University of Colorado - Dr Monet



The following devices were brought to the University of Colorado for a meeting with Dr Monet to discuss plans for an upcoming animal study. Devices included were: Prototype delivery device (1), Harness with drive cable (2), 0.032 Harness (3), 0.015 Harness (4), 0.0195 Harness (5), and a harness having variable amplitude height (6).



*[Handwritten signature]*  
3/19/00

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# Shear Strip Anchor Prototypes

## Shear Strip Anchor Prototypes ( continued from page 42, Concept for shear strip anchor) 3/13/00

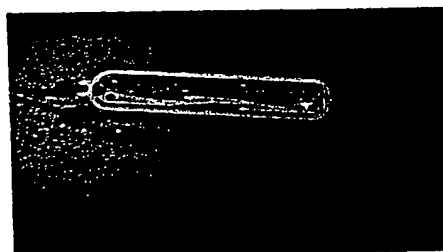
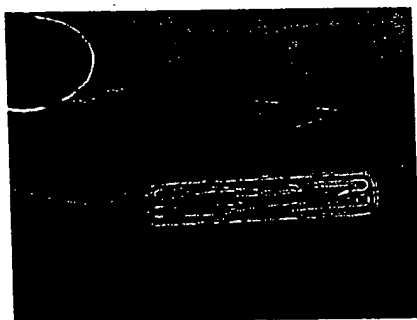
### Description:

The following pictures are completed prototypes of a shear strip anchor concept.

The idea would be two barbed anchors could be tethered between a spring as illustrated in fig. A. The spring would keep constant tension on the epicardium limiting the amount of distension during diastole while allowing some assistance during systole when the system recoils.

Shear strips could also be used to terminate the tether line used with the coil spring anchors. Rather than tying off on the last screw, a shear anchor could be attached to the line as well as an inline spring. This would keep the system in tension and distribute the load into the spring rather than the shear strip.

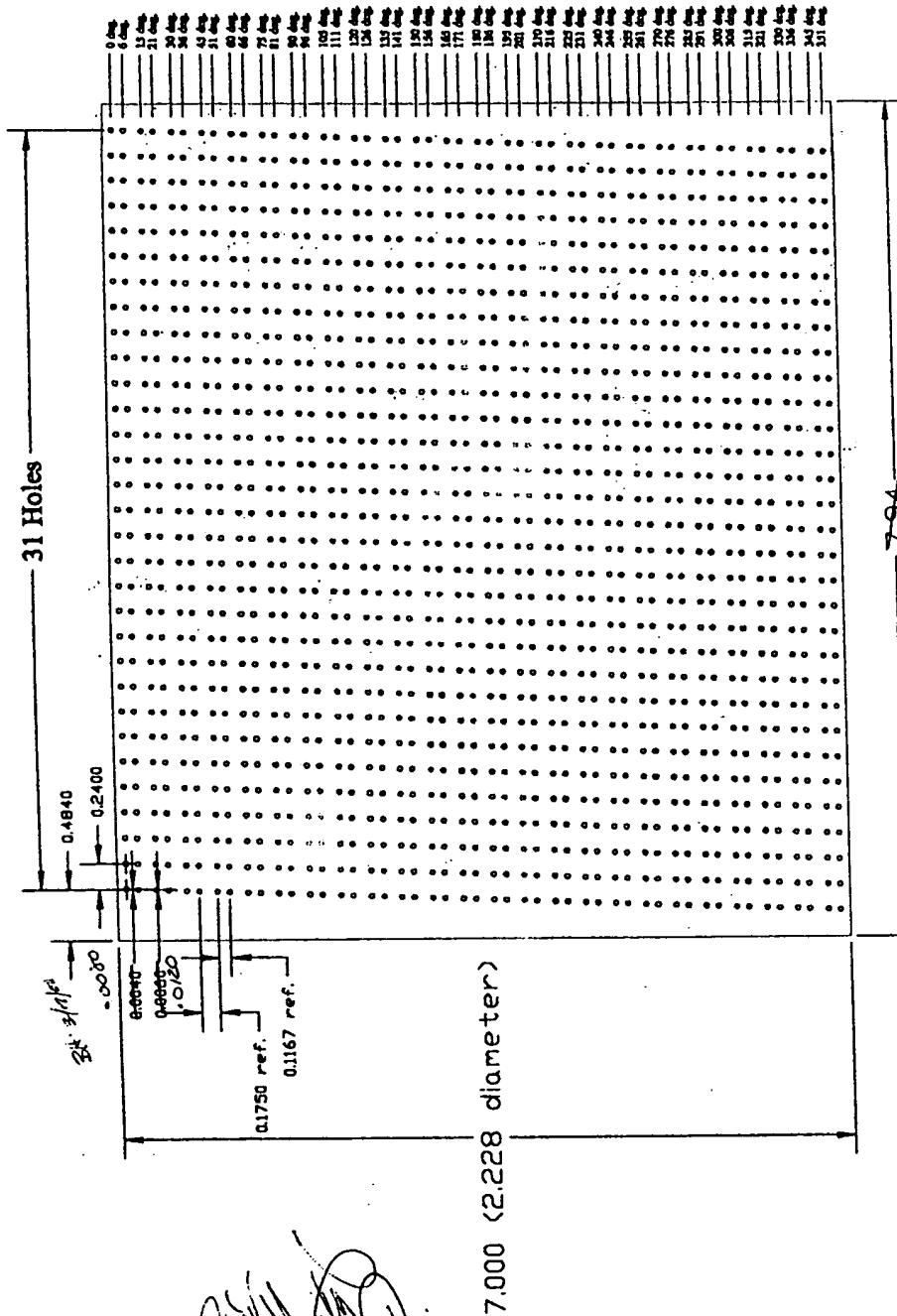
These prototypes were designed to be modular. In the event only one anchor was needed, a single anchor could be cut off and attached using the holes at either end of the strip.



*[Handwritten signature]*  
3/14/00

*[Handwritten signature]* 3/19/00

Outline Model Drawing # HD-1C 3/14/00



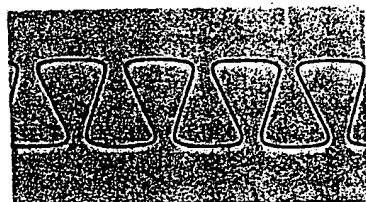
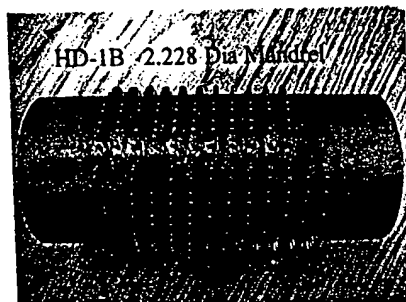
Paracor Surgical, Inc.  
B. Hartigan  
Part # HD-1C  
3/15/00

3/14/00

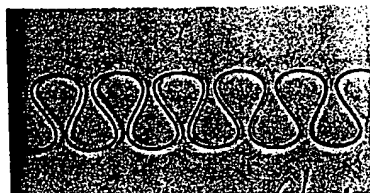
Winding Patterns using Mandrel HD-1 & HD-1B 3/16/00

# Winding Patterns Using Mandrel HD-1 & HD-1B 03/13/00

Description: The following pictures are different wire patterns and diameters using first mandrel HD-1 and then modifying the mandrel by adding a row of pins between the existing rows.



#1 Wire pattern using 0.015 dia. NiTi wire, mandrel HD-1



#2 0.026 Dia. Wire HD-1

*[Handwritten signature]*  
3/16/00

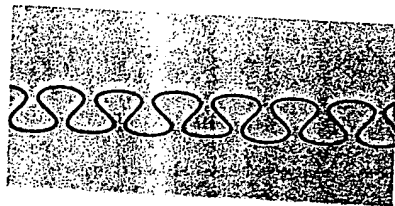
READY UNDERSTAND  
*[Handwritten signature]* 4-12-00



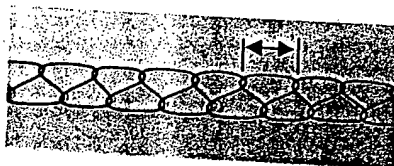
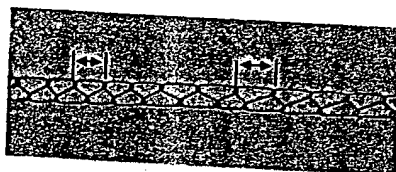
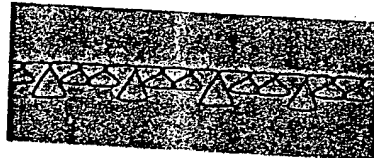
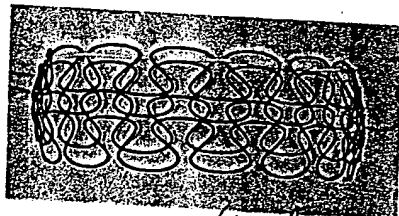
(Cont from Pg 53)

## Winding Patterns Using Mandrel HD-1 &amp; HD-1B

03/13/0



0.015 Dia. Wire Mandrel HD-1B

0.015 Dia wire Mandrel HD-1B  
Wire overlapping pins to allow a  
2-1 expansion ratio.0.015 dia wire  
2<sup>nd</sup> row length changes on bars to  
prevent them from slipping out  
while they are interlocked0.015 dia wire Different pattern  
to prevent last row of wire from  
slipping out after it's interlocked0.019 dia wire with thread to  
prevent last interlocked row from  
slipping out

*[Signature]*  
3/16/00

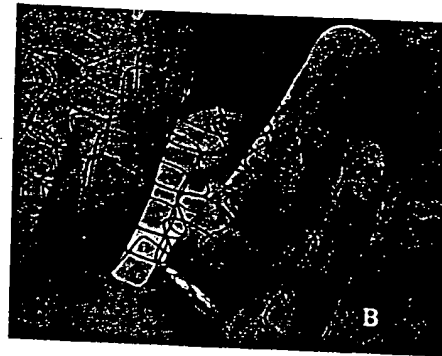
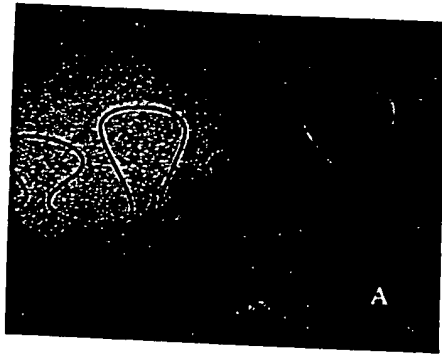
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*[Signature]*

4-12-00

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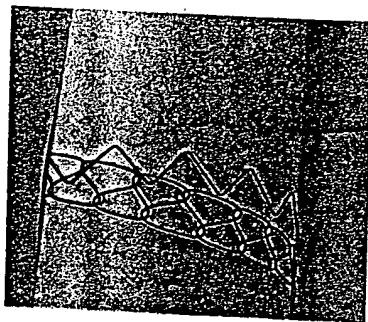
continued next Page.

*[Signature]* 2/10/00



(Above) Variable size undulations

By varying the height of the undulations this allows for a primary and secondary expansion rate as shown in fig. B. The longer pattern has reached its maximum load while the shorter undulations are just starting to distend. The longer pattern has a longer moment arm allowing them to move easier than the shorter arms. This pattern would be beneficial as the longer pattern would be used during diastole, not restricting filling of the chamber while the shorter bars would be activated during end diastole limiting the amount of distension of the heart.



Mandrel HD-1B

Last row is doubled back and using the existing pins to form undulations. Last row is woven into the pattern to stop the last row from coming undone. Undulating pattern still allows for the harness to expand radially



Winding the modified HD-1 *PATERN mandrel*

7.00 (2.2

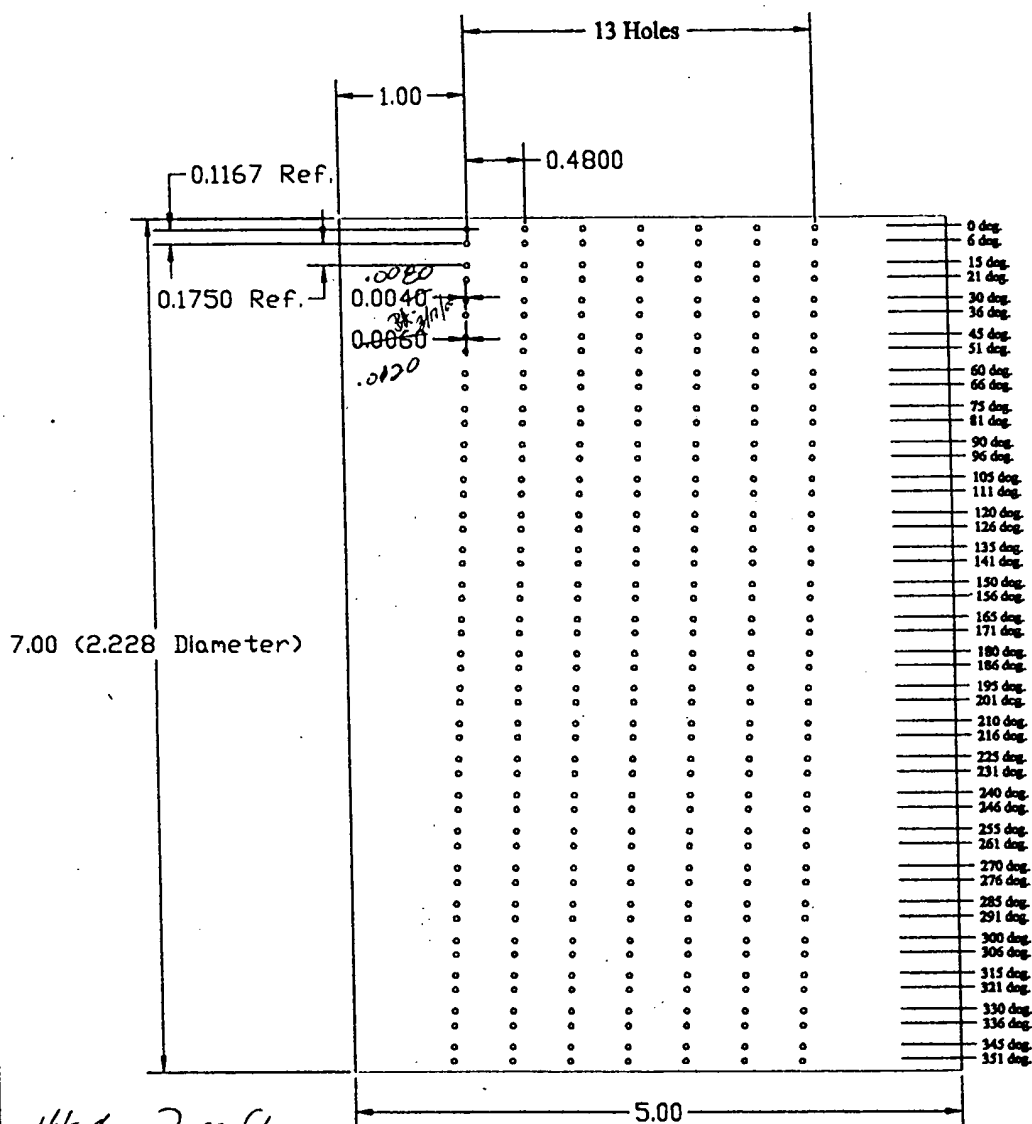
Hole Ø .05

*OKWAS 3/19/00*

HD-1

DRAWING

2/16/00



Hole Ø - Press Fit  
0.0465 Ø Pin

PART#: HD-1

L. LAU

2/17/2000

Paracor Surgical, Inc.

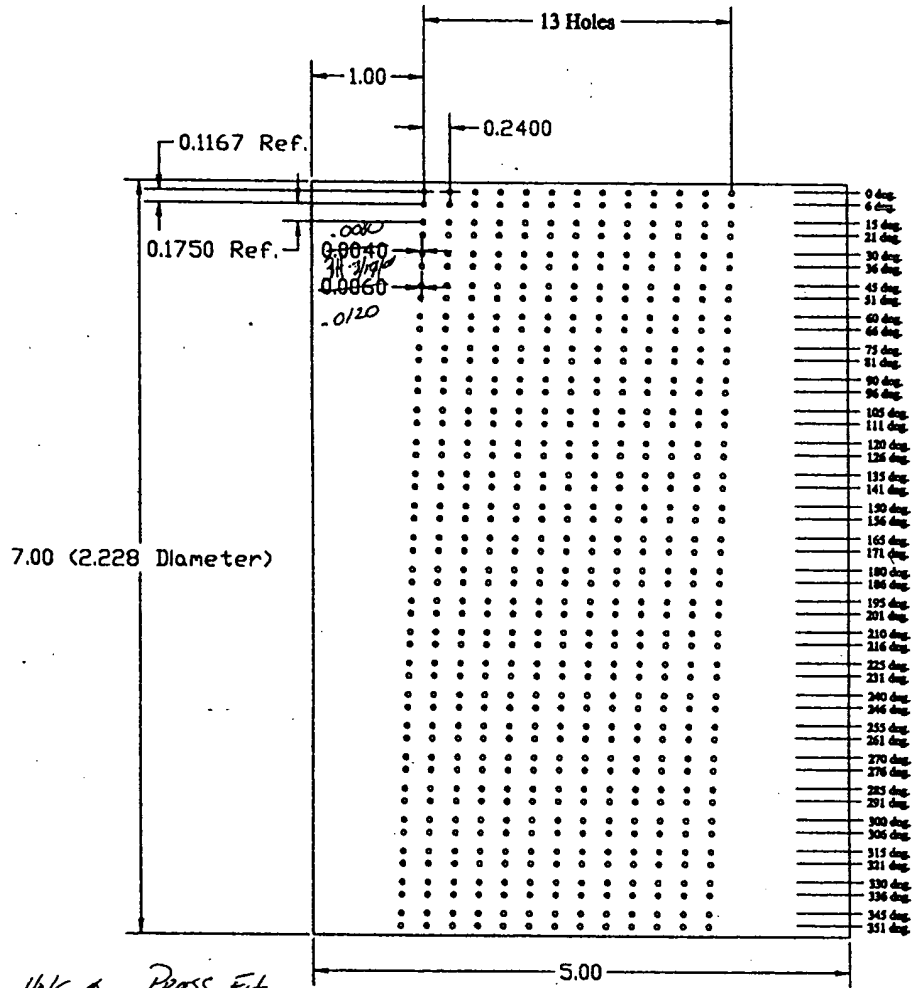
B. Hartigan

Drawing Modified 3/15/00

PART MACHINED @ KODAL ENGINEERING

3/19/00

# HD-1B DRAWING.



Hole  $\phi$  - Press Fit  
 .0469  $\phi$  pin

Paracor Surgical, Inc.  
 B. Hartigan  
 Part # HD-1B  
 3/15/00

*[Signature]*  
 3/15/00

Part machined & KODAL ENGINEERING

*[Signature]* 3/15/00

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